Annual Report 2020

Making a difference to the lives of people affected by bladder, kidney, testicular, penile and prostate cancers
The Directors of ANZUP Cancer Trials Group Limited ("ANZUP") are pleased to submit the Annual Report for 2020

ANZUP Cancer Trials Group Limited

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ANZUP and its members would like to acknowledge and pay respect to the traditional owners of the lands across Australia. We would like to pay our respects to the elders both past and present, and all Aboriginal and Torres Strait Islander people, from whatever nation they may come. In particular, we acknowledge the Gadigal people of the Eora nation as the traditional owners of the lands and waters where our offices are located.
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ANZUP 2019/20 Highlights

**MEmBERSHIP**

*As at 31 March, 2020*

<table>
<thead>
<tr>
<th>Year</th>
<th>Members</th>
</tr>
</thead>
<tbody>
<tr>
<td>2016</td>
<td>1,100</td>
</tr>
<tr>
<td>2017</td>
<td>1,250</td>
</tr>
<tr>
<td>2018</td>
<td>1,300</td>
</tr>
<tr>
<td>2019</td>
<td>1,350</td>
</tr>
<tr>
<td>2020</td>
<td>1,724</td>
</tr>
</tbody>
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**ANZUP & CO-BADGED TRIALS**

**Active trials, including those in follow-up.**

<table>
<thead>
<tr>
<th>Year</th>
<th>Trials</th>
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<tbody>
<tr>
<td>2016/17</td>
<td>9</td>
</tr>
<tr>
<td>2017/18</td>
<td>13</td>
</tr>
<tr>
<td>2018/19</td>
<td>14</td>
</tr>
<tr>
<td>2019/20</td>
<td>16</td>
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**ANZUP TRIAL PARTICIPANTS**

*From over 340 sites*

- 2017: 335
- 2018: 395
- 2019: 416

**PRECEPTORSHIP ATTENDEES**

- 2017: 36
- 2018: 42
- 2019: 40

**ASM DELEGATES**

- 2017: 335
- 2018: 395
- 2019: 416

**CDW WORKSHOPS**

- 2017: 22
- 2018: 32
- 2019: 31

**CONCEPTS ATTENDEES**

- 2017: 98
- 2018: 115
- 2019: 229

*As at 31 March, 2020*
ANZUP 2019/20 Highlights

CORPORATE SUPPORTERS

2019/20

IN-KIND SUPPORTERS

2019/20

WEB PAGE VIEWS

2017 140,912
2018/19 184,028
2019/20 189,856

TWITTER FOLLOWERS

ANZUP

2018 1,891
2019 2,139
2020 2,472

ASM TWITTER IMPRESSIONS

2019 2.75M

ENZAMET TWITTER IMPACTS

2019 8.9M+

FELLOWSHIPS, SCHOLARSHIPS AND AWARDS

2017 47
2018 40
2019 49

(BRINGING TRAVEL FELLOWSHIP, STUDY CO-ORDINATOR, YOUNG INVESTIGATOR AND BEST OF THE BEST)

BELOW THE BELT RESEARCH FUND GRANTS

2017 7
2018 8
2019 6

*As at 31 March, 2020
I am privileged to provide this report on behalf of the ANZUP Board outlining ANZUP’s activities, progress against its Strategic Plan, and state of the Company over the last year.

ANZUP was set up in recognition of the need to have high quality evidence to support clinicians, scientists, and the wider community, as we work together to improve outcomes for people affected by genitourinary cancers. ANZUP and its broad membership recognise that this is best done by performing high quality clinical trials to address areas of identified clinical need, in response to input from the community it serves, and in partnership with that community. The community is everyone affected by these cancers, as well as those providing health care to them, or devising new ideas to be tested, or making discoveries that will lead new treatment, or undertaking the difficult work of translating these discoveries and ideas into real and tangible benefits.

ANZUP’s basic function is to ensure that we build upon progress made to date by ourselves and by others, and that we continue to push the field ahead. The academic and investigator-initiated nature of our clinical trials means that we are not driven by the same imperatives as other parts of the healthcare industry; ANZUP is able to ask and answer the questions that need to be addressed, and can work with multiple partners to do so. These partners frequently include the pharmaceutical industry and other commercial entities, with which we have a strong but independent relationship that has been highly fruitful, as events of the past year have shown.

ANZUP also recognises the value of investing for the future. We do this in several ways. Perhaps the most important is our investment in future clinicians, researchers, and advocates. ANZUP has developed over the years several educational initiatives, which have been avidly sought after by clinicians and researchers early in their careers, but have also provided benefits for those who are more established. These initiatives include the educational components of our Annual Scientific Meeting and associated symposia and other meetings; training, travel, and other fellowships; preceptorship courses, in Australia and overseas; consensus meetings; and “Best of GU” and similar educational events. We have provided opportunities for ANZUP members of all disciplines, and have set up systems to ensure we maintain multidisciplinary input and diversity. We run regular Concept Development Workshops, encouraging researchers of all levels of experience to contribute ideas that can then be further developed in concert with other experienced researchers.

We have strong links with external stakeholders: international organisations with similar objectives; coordinating centres such as the University of Sydney NHMRC Clinical Trials Centre, or the Biostatistics and Clinical Trials Centre at University of Melbourne; philanthropy and funding organisations; advocacy groups; and other Australian and New Zealand cooperative cancer clinical trials groups with complementary objectives. These strategies are already bearing fruit, as several ideas have evolved into successful trials, and as we see individuals and groups growing in experience, confidence, skill, and their commitment to achieving ANZUP’s wider vision. This has led to a growing need for more effective communication strategies internally and externally, and thinking about better ways to engage the wider membership.

ANZUP’s current Strategic Plan 2018-2020 is soon due to be refreshed. It contains several specific strategic priorities, and I am delighted to be able to report significant progress against all of these, and against the specific objectives outlined in the underlying operational plan. These processes are overseen by our highly-engaged Board, and implemented through our CEO Margaret McJannett and her excellent team. The Board is comprised of directors elected from the ANZUP membership, and directors appointed on the basis of their skills and experience. The Board is highly functional and has an effective governance and risk management structure, including for its financial and other corporate responsibilities. The Board is advised by the Scientific Advisory Committee (SAC) in terms of scientific direction for ANZUP trials and other activities. The Board, the SAC, and all the SAC subcommittees are advised by the Consumer Advisory Panel, ensuring that the needs of people affected by genitourinary cancers are always the priority, and that there are clear conduits for two-way communication with the broader community. This governance structure enables effective running of the Company, and ensures that our strategic objectives can be achieved and surpassed. This requires regular review and reflection, and occasionally reprioritisation, as the clinical and scientific landscapes continue to evolve, and as opportunities and challenges arise.
ANZUP’s reporting year is from 1 April to 31 March. This year has seen some extraordinary high points for the organisation, and some significant challenges. I will summarise some of these points in reference to the specific goals outlined in the Strategic Plan.

Goal 1. Continue to build on and develop high quality cutting edge clinical trials.

Some of the highlights of ANZUP’s trial successes are described elsewhere in this report. Other ANZUP trials continue to recruit. Successful Concept Development Workshops were held in April and May 2019, resulting in new ideas to be taken forward into new trials. Significantly, one concept was chosen through this process as the next trial for support through the collaboration between ANZUP and the Prostate Cancer Foundation of Australia. Other trials received grant funding from Movember or other bodies and are also now well advanced in development. All of this activity points to the effectiveness of our processes from some years ago, when trials like ENZAMET were conceived; and to the effectiveness of our new and evolving processes, with new studies continually under development and with considerable external interest. One such study is the DASL-HiCaP international prostate cancer, developed and led by ANZUP in collaboration with several international groups and with support from Bayer. This prostate cancer trial was poised to enter its first patient at the end of this reporting year.

Goal 2. Increase awareness, participation and access to ANZUP trials.

ANZUP receives funding through Cancer Australia and part of that funding is contingent upon our ability to meet certain metrics, including numbers of trials, number of trial participants, number of sites including new sites, and engagement of rural, regional, and remote sites. ANZUP has been able to meet all of these metrics, and we continue to look for more opportunities to involve researchers, sites, and regions, including specific planning for involvement of New Zealand sites. ANZUP is also investigating the use of telehealth approaches to facilitate “teletrials” so that geographically remote participants are able to take part. The success of trials like ENZAMET has launched ANZUP on the international stage, where we have a strong reputation for quality and for asking relevant clinical and research questions. Locally, our continued success in this goal will require effective communication with our members and with external stakeholders and the broader community. ANZUP has built its internal capacity to ensure that these needs can be met.

Goal 3. Strengthen and build our capacity and capability to ensure we can deliver our Strategic Plan.

ANZUP has reviewed its governance processes and established a Board governance subcommittee to this end. We have carefully assessed our financial situation, including investment of surplus funds in order to provide for future lean times, or to support our mission in the event of lack of competitive funding. We have continued to build our fundraising capacity and have seen several new initiatives this year that have raised our profile further and provided opportunities to build new partnerships and reach into new avenues for fundraising. This will allow us to support specific research projects and individuals, and eventually to support specific projects, perhaps in their entirety. Our central office team has been strengthened to build our capability to take on sponsor responsibilities for our trials. This is necessary to ensure that the intellectual property generated by ANZUP remains under our control, and also allows us to ensure that we can work with groups and systems as required to achieve our goals. Our growth in support for grant awardees or specific projects represents an investment in the future that will also grow our capacity and capability in the long term. ANZUP was delighted to be able to establish two new awards, the Noel Castan fellowships, to enable bioinformatics research and quality of life research, thanks to the generosity of Anita Castan.

Goal 4. Engage, collaborate and enhance mutually beneficial relationships.

The nature of ANZUP and the work that we do means that we are always aware of our dependency on, and support for, other organisations with complementary objectives. ANZUP has built strong collaborative links that amplify its effectiveness in performing high quality research in Australia, New Zealand, and now internationally more broadly. We have built new relationships, and have refreshed or are refreshing old ones. The DASL-HiCaP study is an example, where we have continued our previous successful work with Cancer Trials Ireland and with the Canadian Cancer Trials Group, and have now established new links with the Prostate Cancer Clinical Trials Consortium that will enable the trial to be run at multiple sites in the USA.
Goal 5. Increase engagement of the membership. ANZUP comprises a diverse group of clinicians, researchers, community representatives, and others.

Our membership has continued to grow but we recognise that the majority of our members are not always deeply engaged. However, we have seen new people becoming active in our committees and subcommittees, with new appointments to the SAC, and new people taking the lead in development of concepts at our workshops, or through our Below the Belt research funding strategy. We continue to look for gaps and opportunities to build on our multidisciplinary membership. We continue our programs of support for early and mid career researchers, including mentorship, training, grants, travel and research support, and specific educational opportunities. ANZUP recognised potential gaps in its genitourinary portfolio, where our Bladder subcommittee was the de facto group to review other urothelial or rare genitourinary cancers. This has now been rectified by relaunching that committee as the Bladder Urothelial Penile (BUP) subcommittee, ensuring for the first time that rarer urinary cancers or penile cancers now have a defined place in our organisation.

Goal 6. Broaden ANZUP’s profile in the community locally, nationally and internationally.

This year was highlighted by the reporting of the ENZAMET trial as a Plenary Presentation at the American Society of Clinical Oncology (ASCO) 2019 Annual Meeting in June, with simultaneous publication in the New England Journal of Medicine, less than three months after the results were known. This attracted widespread international interest, followed by approval of this agent and this indication by the US Food and Drug Administration in December 2019. This means that ANZUP-led research has changed the face of clinical practice internationally, for the benefit of our patients. Subsequent work on the health-related quality of life aspects of ENZAMET was presented in September at the European Society of Medical Oncology annual meeting. The TheraP phase 2 trial comparing Lu-177-PSMA to cabazitaxel completed accrual in late December 2019 and was accepted for oral presentation at ASCO 2020.

This year has brought challenges to us, which we share with the wider society. The coronavirus COVID-19 pandemic had significant effects on many of our activities. Many sites were unable to continue clinical trial recruitment. The ANZUP central team needed to set up quick and effective systems for spatial distancing and working from home. Our Concept Development Workshops required replanning to be virtual meetings. A planned Asia-Pacific meeting to update our regional recommendations from the Advanced Prostate Cancer Consensus Conference, planned to be held in Singapore, had to be deferred until later in the year. Most significantly, it rapidly became clear that we would be unable to hold our Annual Scientific Meeting for 2020 as planned. These events caused significant disruption to all of our programs, and a clear threat to our planned financial position. ANZUP is a not-for-profit company and is a registered charity. We must be careful about our financial management. We have invested surplus revenue carefully and in socially responsible investments. COVID-19 affected the value of these investments but not as severely as it might otherwise have done. Our judicious financial planning over many years gave us the reserve to be able to continue to operate for many months even in the extreme situation of no revenue whatsoever, which of course was not the case. The Board met and agreed that we would be able to absorb the loss of revenue from the ASM, our major source of non-trial revenue. The CEO and her team together with the Board and many other committed ANZUP members have put effective systems in place to mitigate the financial and other adverse effects of the crisis, and we have been able to continue many aspects of our work. It has required some creativity in virtual running of events and meetings, and extensive but rapid replanning of major components such as the ASM, but the Board is confident that we have weathered the crisis effectively so far and are well positioned to continue to do so.
This year has clearly been a rollercoaster adventure, but the organisation remains strong and effective, and is clearly meeting all of its strategic goals and corporate responsibilities. I would like to give my personal thanks and gratitude to my fellow directors, who contribute extensively, effectively, and with extraordinary generosity to ANZUP in so many ways. Our secretariat and our volunteer team, led so ably by our CEO Margaret McJannett, continues to perform at a very high level and to achieve things I would not have thought possible.

In closing, I would be remiss if I did not highlight two specific people, who quite literally were responsible for ANZUP coming into existence and for its success. The first is A/Prof Guy Toner. Guy chaired the ANZUP predecessor group, the ANZ Germ Cell Trials Group, for many years prior to its merging and evolution to become ANZUP. Guy has served as ANZUP Board director and deputy chair since its inception, and as one of the nominated medical oncology representatives on the SAC. He is the quiet voice of reason and wisdom behind most of what we have achieved. He has overseen the growth and development of many of our initiatives, including the Below the Belt Research Fund. He has provided mentorship and support, and generously shared his encyclopedic knowledge and expertise and gentle wisdom, to many of us, including me. Guy is now transitioning into retirement and we wish him every happiness in this next phase of his life. The other person is Prof Pam Russell. Pam is internationally renowned for her prostate cancer research and support and mentorship of junior scientists and clinicians. Pam was also a founding Director of ANZUP and was the scientist representative on the SAC. Pam has continued to be productive at every level far past the points to which most people might only aspire, but stepped back from the Board several years ago and is now standing down from her position on the SAC. ANZUP probably would not exist, and certainly would not have survived its infancy, without the contributions of both Guy and Pam, and we will be forever grateful to them both.

Thank you all for your interest and involvement in ANZUP. I commend to you this 2019-2020 Annual Report of ANZUP Cancer Trials Group.

Ian Davis
Director and Chair of the ANZUP Board
As the decade drew to a close and we leapt into the 20’s, ANZUP not only grew in terms of trials and membership but also achieved a number of significant milestones over the past 12 months.

In June 2019, we celebrated a major achievement with our ENZAMET trial featuring as a Plenary Session at the 2019 American Society of Clinical Oncology (ASCO) Annual Meeting. It certainly propelled us onto the international stage! Special thanks to the Study Co-chairs, Ian Davis and Christopher Sweeney for their commitment and leadership and to our local and international investigators from across the 85 sites, our collaborators at the NHMRC CTC, Cancer Trials Ireland and the Canadian Cancer Trials Group, and to the 1125 patients who participated on the trial.

Our thanks to Astellas for their support in terms of funding and product to conduct both the ENZAMET (ANZUP 1304) and ENZARAD (ANZUP 1303) trials.

In December 2019 enzalutamide received U.S. FDA approval for treatment of men with metastatic hormone-sensitive prostate cancer, this decision being supported by data from the ENZAMET trial. A great achievement and one we hope to see followed by other countries around the world including Australia and New Zealand.

ANZUP’s approach to all of its clinical trials is to centre the research question on its value to the community.

ANZUP’s ENZAMET trial was again recognised by ASCO on World Cancer Day (4 February 2020) in its Clinical Cancer Advances 2020: ASCO’s Annual Report on Progress Against Cancer. The report highlighted the most important clinical research advances of the past year and identified priority areas where ASCO believes research efforts should be focused moving forward.

You can read more about ENZAMET and these achievements from page 28.

ANZUP’s clinical trials portfolio continues to grow across the major cancers we represent. Currently we have 7 ANZUP-led active and recruiting trials, 4 co-badged trials, 8 protocols in development, 31 concepts presented across 6 concept development workshops; and 6 Below the Belt Research Grants awarded in July 2019.

During the course of the year three of our trials reached their recruitment targets; TheraP (ANZUP 1603), UNISO N (ANZUP 1602) and Pain Free TRUS B (ANZUP 1501).

In September 2019 the last patient was randomised to our TheraP trial, five months ahead of schedule. At the time of writing this report, Study Chair Michael Hofman has been offered an oral presentation of the interim study results at the 2020 Virtual ASCO meeting in May 2020. A wonderful collaboration between ANZUP and the Prostate Cancer Foundation of Australia with support from Movember, It’s a Bloke Thing Foundation, Can4Cancer, Endocyte (A Novartis Company), Australian Nuclear Science and Technology Organisation (ANSTO). Congratulations to Michael and the multidisciplinary team of investigators, study coordinators, nuclear medicine technologists, radiopharmacists, clinical research associates and data managers.

ANZUP is committed to finding better treatments for our patients and their families affected by GU cancer through our clinical trials research.
Our UNISoN trial (ANZUP 1602) also reached its target of 85 patients, nine months ahead of the planned recruitment. Many thanks to Study Chair Craig Gedye, for his leadership as well as the entire UNISoN team across Australia who did an amazing job on this important non-clear cell kidney cancer trial.

In November 2019 the Pain Free TRUS B team reached its target of 420 patients – yet another very significant milestone! Congratulations to Nick Buchanan and his team of investigators across Australia and New Zealand.

There are also a number of exciting new studies due to open in early 2020 – including DASL-HiCaP (ANZUP 1801) and ENZA-p (ANZUP 1901) and our co-badged study #UpFrontPSMA.

We are extremely grateful to all the patients for their amazing contributions to these trials in order for us to improve treatment and outcomes for our community.

Our 2019 Annual Scientific Meeting (ASM) was yet another major achievement attracting close to 400 delegates to Brisbane across the three days. The theme ‘Making Connections’ explored how we can improve patient / carer / clinician access to the right information, including supportive care and clinical trials, while encouraging links between the various disciplines, researchers and cross border collaborations. We are extremely grateful to the dedicated and hardworking convening committee led by the ever-thoughtful David Pryor developing a program that provided us with the most up to date scientific presentations from an impressive national and international faculty. We thank Kelly Parsons, Phuoc Tran, Alison Birtle, Catherine Paterson and Betsy Plimack who shared with us their insights, expertise and “talent” to ensure another high quality and innovative program that had something for everyone!

This year marked the 6th year of the Below the Belt Pedalthon in Sydney and our second Pedalthon in Melbourne. Since its inception in 2014, we have raised over $1.75 million which has helped provide much needed seed funding to support our members to progress their new trial ideas to the point of becoming full scale studies. Thanks to every supporter; participant and donor for helping us reach this amazing goal.

Strategic & Business Planning:

We are currently operating under the 2018-2020 Strategic Plan. The ANZUP Board, Governance, Finance & Audit, Fundraising and Promotion committees continue to meet regularly across the year as well as the Scientific Advisory Committee (SAC), Consumer Advisory Panel (CAP) and Trials Operations committees. These meetings help to ensure our ANZUP activities are aligned with our overarching Mission and Strategic Plan.

The ANZUP Board looks forward to sharing our 2021 – 2023 Strategic Plan later in 2020.

Finances:

As a not-for-profit research group, ANZUP continues to receive valuable infrastructure funding from the Australian Government through Cancer Australia, whilst concurrently building greater financial independence and self-sufficiency through a number of fundraising avenues.

A key feature of clinical trial research is it’s time consuming and expensive nature. As a consequence, ANZUP continues to seek sustainable and innovative funding options to ensure our research continues to grow, including our annual ASM, bi-annual Pedalthon’s and fundraising events which both aid in allowing us to instigate trials as well as support funding applications for those with research interests in the GU cancer field.

For further details on ANZUP’s finances, please see from page 54.

Data and quality:

ANZUP works closely with the coordinating centres (NHMRC Clinical Trials Centre and the Centre for Biostatistics and Clinical Trials) to achieve quality processes on trial development and operations. Each organisation uses quality management systems, standard operating procedures (SOPs) and templates for accuracy and consistency. Data systems undergo vigorous planning, programming and checking processes prior to going live. Monitoring and formal audit processes complement these activities and annual training is provided to significant site staff to ensure data quality is maintained. All procedures and data systems comply with national and international guidelines on the conduct of clinical trials.

ANZUP also has an Independent Data and Safety Monitoring Committee (IDSMC) to evaluate the plausible benefits and risks associated with patient participation in ANZUP trials, and assess whether this justifies continuing the trials according to their original design. The IDSMC periodically reviews trial data and informs the ANZUP SAC Chair and relevant Trial Management Committee (TMC).
Staffing:
In line with ANZUP’s strategic plan we have expanded the management team to ensure we have the necessary skill-set and experience to support our membership to achieve our Mission. As we continue to build on our partnerships and collaborations we are reviewing our staffing in the key areas of clinical trials management and database coordination and support, internal and external communications, event production and promotion, fundraising and corporate partnerships and administrative support.

We are very fortunate to have such a dedicated management team who work tirelessly to support our ANZUP membership and their research endeavours.

Education and mentoring:
To further improve health outcomes for patients, ANZUP continues to seek opportunities to expand on educational and mentoring opportunities for our membership. The next generation of scientists and clinical researchers are very important to us, as they will pave the way for clinical trials to come. We host a variety of events targeted to junior researchers, in efforts to further their education and burgeoning clinical concepts.

The ANZUP ASM continues to be a well-attended event, and one of the key events in Australia to discuss the latest updates in GU cancer research, treatments and supportive care with outstanding international faculties comprised of experts in the field in attendance. Our highly popular MDT Masterclass, part of the ASM program, is another key educational and mentoring experience for attendees, which incorporates a series of interactive care-based discussions across each of the major genitourinary cancers.

ANZUP’s Concept Development Workshops are another vital ANZUP activity aimed at educating and mentoring our membership. The Workshops, held across the cohort of cancers ANZUP represents, provide an opportunity for early-career researchers to receive mentorship whilst sharing ideas for emerging clinical trials. In the 2019/20 reporting period we held 5 Workshops, with 43 concepts presented and 229 attendees. Impressive numbers and growing each year.

Following ASCO in June 2019, ANZUP in partnership with Astellas Oncology, hosted our inaugural Prostate Cancer Masterclass in Boston. This 2 ½ day Masterclass, was convened by Professor Chris Sweeney, and provided a comprehensive update on current best practice, emerging clinical evidence, and recent expert opinions in prostate cancer management. Six ANZUP members were selected to attend this unique and insightful training opportunity.

On 29 and 30 November, ANZUP held its 4th GU Preceptorship in Prostate Cancer covering landmark clinical trials with mentorship from experts in the field. These multidisciplinary interactive educational workshops have proved highly successful, attracting trainees and junior consultants over the course of the 1 ½ days of intense learning under the guidance of the Preceptors; Jarad Martin, Amy Hayden, Venu Chalasani, Shahnne Sandhu, Henry Woo, Jeremy Shapiro and Louise Emmett, and skilfully convened by Professor Eva Segelov. We are very grateful to our Corporate Partners who provide the sponsorship so we can host these educational opportunities for our members.

As we reflect on the last 12 months it’s important to acknowledge and thank all the truly amazing and dedicated people who continue to take time out of their very busy schedules to support and contribute to ANZUP.

The Board – led by our Chair Prof Ian Davis, Deputy Chair A/Prof Guy Toner, Prof Henry Woo, Dr Nick Buchan, Prof Shomik Sengupta, Mr Glenn Ferguson AM, Mr Joe Esposito, Mr Martin Dowling and Ms Linda Martin – continue to give their expertise, time and support so generously, guiding the organisation’s strategic direction.

We are also extremely grateful to the SAC, Subcommittee chairs, Deputy chairs, our CAP, Study Chairs, Site Investigators and the hundreds of Trial Staff and members; ANZUP would not exist without you and we certainly wouldn’t have achieved what we have without your tireless efforts.

To our wonderful volunteers Lesley Tinkler and Jo Stubbs, our colleagues at NHMRC CTC and BaCT, our corporate supporters, sponsors and donors, thank you for your support and your invaluable contribution.

Finally our thanks to the many thousands of patients who participate in our ANZUP trials. Each and every one of you help us to achieve our mission: To improve treatment and outcomes for patients and their families affected by these below the belt cancers.

Margaret McJannett
Chief Executive Officer, ANZUP
Governance Structure

ANZUP Cancer Trials Group Ltd is a collaborative, national and international, urogenital and prostate cancer, clinical trials, and research group. The organisational structure of ANZUP reflects its corporate governance and operational areas of responsibility.

Board
The Board comprises the Directors of the Company and is responsible for financial management, corporate governance, reporting and compliance. The Board consists of five elected Directors and four Appointed Directors. The Board meets by teleconference approximately once every two months and face-to-face several times per year.

Governance Committee
The purpose of the Governance Committee is to ensure that the Board fulfills its legal, ethical, and functional responsibilities through adequate governance policy development, recruitment strategies, monitoring of Board activities, and evaluation of Board members’ performance.

Finance and Audit Committee
A committee of the Board. Its main objectives are to assist the Board in the discharge of its responsibility to exercise due care, diligence and skill; and to provide a formal forum for financial management, compliance and control.

Fundraising and Promotion Subcommittee
A subcommittee of the Finance and Audit Committee. Its main objectives are to identify and pursue opportunities for additional revenue through fundraising and production of relevant marketing materials for ANZUP.

Management Team
The Management team comprises the Chief Executive Officer (Margaret McJannett, 1 FTE), Executive Assistant (Alison Martin, 1 FTE), Marketing and Communications Manager (Lucy Byers, 1 FTE), Internal Communication and Projects Manager (Nicole Tankard, 1 FTE), Marketing and Communications Officer (Gillian Bailey, 0.7 FTE), Clinical Trials Project Manager (Nisha Rama, 1 FTE), Head of Partnerships and Engagement (Julijana Trifunovic 0.7 FTE) and Database and Administration Coordinator (Nima Amatya, 1 FTE). The company’s registered office is in Sydney.

Consumer Advisory Panel (CAP)
The ANZUP CAP reports to the Board. It comprises consumer/community representatives who contribute at all levels of governance, from the Board and SAC and its subcommittees through to specific trials and research projects. The CAP also provides a conduit for communication from ANZUP back to the community in order to promote clinical trial research. The CAP meets by teleconference quarterly and intends to meet face-to-face at least once per year where resources permit.

Scientific Advisory Committee (SAC)
The SAC consists of a core of members representing the major disciplines relevant to ANZUP, nominated and appointed upon the recommendation of those groups. In addition, Chairs of the SAC subcommittees are members of the SAC by virtue of their appointment as Chair. The SAC meets by teleconference quarterly with one annual face-to-face meeting during the ASM.

SAC Subcommittees
The SAC is advised by disease specific subcommittees (Prostate, Renal, Germ Cell and Bladder/Urothelial/Penile) and non-disease-specific subcommittees (Quality of Life & Supportive Care and Translational Research). The disease-specific subcommittees are responsible for oversight of trials within their portfolios, as well as development of new trial concepts. These subcommittees meet by teleconference quarterly and intend to meet face-to-face at least once per year. The non-disease-specific subcommittees are involved as required in trial development and management in order to ensure maximum value is added to every trial. These subcommittees meet by teleconference as required and intend to meet face-to-face at least once per year.

Operations Executive Committee
This committee consists of representatives from ANZUP and each of its coordinating centres - the NHMRC Clinical Trials Centre at The University of Sydney and the Centre for Biostatistics and Clinical Trials. The committee is responsible for oversight of trials and group operations. This committee meets by teleconference approximately once per month.

Independent Data Security Monitoring Committee (IDSMC)
The broad aim of the IDSMC is to evaluate the plausible benefits and risks associated with patient participation in ANZUP trials. The IDSMC comprises at least three members who are experienced in clinical research and are not conflicted with ANZUP. The committee oversees a number of ANZUP studies and co-opts others onto it when additional advice is required. The IDSMC advises the relevant Trial Management Committee (TMC) Chair(s), Group Chair and Scientific Advisory Committee Chair.

Trial Management Committees (TMC)
Each trial has a TMC that meets approximately quarterly by teleconference to ensure oversight of the trial.
Governance Committee

SCIENTIFIC ADVISORY COMMITTEE

Ian Davis – Chair
Martin Stockler – Deputy Chair (till Mar 2020)
Scott Williams – Deputy Chair (from Mar 2020)
Arun Azad
Nicholas Buchan
Suzanne Chambers AO
Warick Delprado
Haryana Dhillon
Joe Esposito
Craig Gedye
Fritha Hanning
Lisa Horvath
Dickon Hayne
George Hruby
Belinda Jago
Anthony Joshua
James Kench
Andrew Martin
Catherine Paterson
David Pook
Pamela Russell (resigned Mar 2020)
Kathryn Schubach
Shomik Sengupta
Christopher Sweeney
Bertrand Tombal
Guy Toner
Ben Tran

Ex-officio
Margaret McMennatt
Jaclyn Verghis (till Dec 2019)
Nisha Rana (from Nov 2019)
Elizabeth Liow
Jane So
Felicia Roncolado
Alison Hall
Sonia Yip
Alison Zhang

FINANCE AND AUDIT COMMITTEE

Joe Esposito – Chair
Bernadette Crennan
Ian Davis
Martin Dowling

Ex-officio
Margaret McMennatt
Glenn Murray
Katie Pancari

FUNDRAISING AND PROMOTION SUBCOMMITTEE

Joe Esposito – Chair
Ray Allen
Bernadette Crennan
Ian Davis
Belinda Jago

Ex-officio
Margaret McMennatt
Lucy Byers
Juliana Trifunovic (from Aug 2019)

CONSUMER ADVISORY PANEL

Belinda Jago – Chair
Raymond Allen – Deputy
Joe Esposito

Ex-officio
Belinda Jago

SUBCOMMITTEE

BUP (Bladder, Urothelial and Penile Cancer):
Dickon Hayne – Chair
Shomik Sengupta – Deputy Chair

Germ Cell:
Ben Tran – Chair
Fritha Hanning – Deputy Chair

Prostate Cancer:
Scott Williams – Chair
Lisa Horvath – Deputy Chair

Quality of Life & Supportive Care:
Haryana Dhillon – Chair
Catherine Paterson – Deputy Chair

Renal Cell Cancer:
Craig Gedye – Chair
David Pook – Deputy Chair

Translational Research:
Arun Azad – Chair
Anthony Joshua – Deputy Chair

ANZUP Fellows:
Elizabeth Liow
Jane So
Sonia Yip
Alison Zhang

ANZUP & CENTRE FOR BIOSTATISTICS & CLINICAL TRIALS (BaCT)

Operations Executive Committee:
Ian Davis – Chair
Craig Gedye – UNISoN
David Pook – UNICAB
Andrew Weickhardt – PCR MIB
Carole Harris
Margaret McMennatt
Jaclyn Verghis (until Dec 2019)
Nisha Rana (from Nov 2019)
Alison Hall – Business Manager (from Nov 2019)
Alan Herschhal – Senior Biostatistician (until Feb 2020)
Komal Kanojia – Project Manager
Deepti Pandey (from Jan 2020)
Amanda Seegum – Trial Coordinator
Thanks to Corporate and In-kind Supporters

Corporate Supporters
We are very fortunate to have our corporate supporters and partners who enable ANZUP to better support our members and, ultimately, patients and their families. Our 2019/2020 corporate supporters include:
Astellas, AstraZeneca, Bayer, Bristol-Myers Squibb, Ipsen, Janssen and Pfizer Oncology.

In-Kind Supporters
We acknowledge and thank the following organisations for the generosity they have shown by providing their services pro-bono.
Active Display Group, AFI Branding, The Saturday Paper and FC Lawyers.
Number of members

As at 31 March 2020 ANZUP had 1,724 members which is an increase of 14% since 1 April 2019.

Membership distribution

BY STATE/TERRITORY IN AUSTRALIA:
- QLD: 247
- NSW: 584
- VIC: 494
- WA: 91
- SA: 99
- NT: 9
- TAS: 22
- ACT: 32

NEW ZEALAND:
- NZL: 103

AUSTRALIA/NEW ZEALAND TOTAL: 1,578

REST OF THE WORLD:
- US: 12
- Canada: 7
- UK: 7
- Ireland: 4
- Belgium: 2
- Malaysia: 2
- Singapore: 2
- China: 1
- India: 1
- Switzerland: 1
- France: 1
- Germany: 1
- Spain: 1

REST OF THE WORLD TOTAL: 43

Building our multidisciplinary membership

- Clinical Trials Coordinator: 321
- Trainee: 274
- Medical Oncologist: 264
- Registered Nurse: 213
- Urologist: 173
- Radiation Oncologist: 122
- Scientist: 77
- Allied Health: 64
- Nuclear medicine: 35
- Students: 32
- Psychologist: 27
- Supportive care: 20
- Fellows: 18
- Pathologist: 16
- Pharmacist: 11
- Statistician: 11
- Consumer Advocacy: 9
- Epidemiologist: 9
- Radiologists: 6
- Endocrinologist: 6
- Health economics: 5
- Surgeon: 3
- Radiation Therapist: 3
- Medical Physics: 2
- Anaesthetist: 2
- General Practitioner: 1
- Psychiatrist: 1

Clinical Trials Coordinator: 321
Trainee: 274
Medical Oncologist: 264
Registered Nurse: 213
We are grateful to all the individuals, families, volunteers, corporations, workplaces and other organisations who supported us this year, and helped ANZUP reach their goals. The generosity of the community helps us fund worthwhile projects, novel nimble trials, or bridge the gap when government grant funding is not enough to complete our work. With growth of our supporter base and opportunities to raise more funds, the Board made the decision to introduce a new fundraising role. In August 2019, Julijana Trifunovic was employed as Head of Partnerships and Engagement for the organisation. Julijana will be supporting the board’s direction and implementing a fundraising strategy to help grow sustainable, cost effective and regular revenue streams through fundraising.

**Community Support**

**The Noel Castan Fellowship**

ANZUP was delighted to launch the Noel Castan Fellowship at the 2019 Annual Scientific Meeting (ASM) in Brisbane. The Noel Castan Fellowship was established by Anita Castan, in memory of her husband, who passed away from cancer two decades ago. “I understand the value of supporting clinical trials and take this opportunity to congratulate ANZUP on its many successes to date and its collaborative approach.”

The aim of the Noel Castan Fellowship is to build ANZUP’s research capacity and increase the translation of information collected from our trials, which will contribute to better understanding of how to optimise patient care.

The Noel Castan Fellowship was awarded to members, Hui-Ming Lin and Kathryn Schubach. Hui-Ming Lin’s ‘Bioinformatics’ project is an analysis of the lipidomic and cytokine profiles from ANZUP’s ENZAMET study, which may identify novel biomarkers from the enzalutamide response, and provide new therapeutic targets to overcome enzalutamide resistance to improve the outcome of prostate cancer patients. Kathryn Schubach’s ‘Quality of Life’ project will develop new questions in trials, using existing data innovatively enhancing and facilitating collaboration and thereby drawing attention and meaning to ‘the patient experience’ and aligning with the mission of ANZUP’s clinical research to improve outcomes.

**Special donations**

In November 2019 one of ANZUP’s key supporters Gary Morgan (Executive Director) and Michelle Levine (Chief Executive Officer) of Roy Morgan Research, donated $100,000 for ANZUP’s clinical trials research into prostate cancer. Gary and Michelle kindly hosted a dinner presentation for ANZUP to help raise awareness and funds for our clinical trial research. ANZUP Chairman Prof Ian Davis and member researcher Assoc. Prof Louise Emmett informed the group about ANZUP’s latest prostate cancer clinical trial research projects. We are extremely grateful for their on-going support.

We are also grateful to Sorbact and Ian Garrow for donating $20,000 to the Below the Belt Fund and launching the Below the Belt Pedalthon Melbourne fundraising with this gift. These pledged funds will be used for a prostate cancer project.
Fundraising Heroes – Bev & John Purvey

A special thank you to Bev and John Purvey for choosing ANZUP as their charity of choice for their 70th birthday party celebration. In lieu of gifts, it was suggested that guests consider a donation to bladder cancer research conducted by ANZUP. Over $10,500 was kindly donated. Bev was diagnosed with bladder cancer in 2018 and is now recovering from her latest treatment. It is her mission to share her experience and inform people about the signs and symptoms of this rare cancer and is happy to tell her story in the future to help raise awareness and even more funds for ANZUP.

The party, held at The Pullman on the Park, Melbourne was a wonderful celebration of their birthday milestone, with over 100 guests including her specialist and ANZUP Member Prof Shomik Sengupta and ANZUP CEO Margaret McJannett. Entertainment for the night was the fabulous Kylie Minogue show. Fun was had by all while supporting a great cause.

Macquarie Bank Morning Tea

On Thursday 8 August, 100 Macquarie Bank staff members attended a charity morning tea organised by the Macquarie Giving Committee to raise awareness and funds for ANZUP.

ANZUP member Assoc. Prof Louise Emmett presented to the group about ANZUP, what we do, and how clinical trials work. Louise also talked about theranostics and the new trial ENZA-p.

The group was then invited to a morning tea and to make a donation to ANZUP. ANZUP T-shirts, hats and water bottles were also available for purchase and proved very popular amongst the Macquarie staff.

It was great to see so many people interested in ANZUP and wanting to learn more about what we do.

The morning tea raised over $5,800 including dollar for dollar matching from Macquarie. A great effort all round!

Our thanks go to Macquarie Bank for making this opportunity possible. A special mention also to Macquarie’s Pedalthon team, the Macquarie Crankers who raised over $7,000 for the Below the Belt Research Fund.

ANZUP’s Trivia Night

ANZUP was delighted to host the inaugural Trivia Night on Thursday 22 August at the Lord Dudley Hotel in Paddington, Sydney.

The event was a great success with a full house of 65 people competing for the trivia master team title and raising over $5,300 for the Below the Belt Research Fund. Congratulations go to the Trials and Trivulations team, trivia champions for the evening. A special mention also goes to 2nd place winners and ANZUP members – Georgie’s Angels led by Patti Bastick.

Our thanks go to the Lord Dudley Hotel for their generous support and hosting the event. Thank you also to prize sponsors – Lisa McGuigan wine, Lion, Flight Centre, Gin Lane and Baby Coffee Co.

Key Partnerships List

ANZUP would also like to acknowledge the below supporters for their kindness.

- Belinda Jago
- Sorbact
- Roy Morgan Research Ltd
- The Lin Huddleston Charitable Foundation
- The Macquarie Group Foundation
- The Nordia Foundation
Below the Belt Research Fund

Every cent we raise through the Below the Belt Pedalthon goes directly towards clinical trial research via the Below the Belt Research Fund.

In 2019, ANZUP’s Below the Belt Research Fund provided much needed seed funding to support six ANZUP members to progress new trial ideas to the point of becoming full scale studies. These research grants were announced at the 2019 ASM in Brisbane.

Andrew Moe: SUBDUE
Our research group is aiming to create a new treatment for patients with bladder cancer.

Durvalumab is a medicine that targets the body’s immune cells to help combat bladder cancer. When given intra-venously, durvalumab has proven effective at slowing advanced bladder cancer that has spread to other organs.

We hope that this treatment can be used in a larger trial, and long-term could become a standard treatment for high-risk bladder cancer.

Ben Tran: CLIMATE
Assessing the Clinical utility of miR-371 as a marker of residual disease in Clinical Stage 1 Testicular Germ Cell Tumour, following orchidectomy. Testicular germ cell tumours (TGCT) are highly curable, even in the metastatic setting where platinum-based chemotherapy is highly effective. Patients diagnosed with clinical stage 1 (CS1) disease are most likely cured following orchidectomy, however, up to 50% do develop recurrence and require intensive courses of curative chemotherapy. A short, less toxic course of adjuvant chemotherapy can be used to reduce the risk of recurrence, but at a significant risk of over treating the large group of patients who will never recur.

CLIMATE is an innovative registry-based translational clinical trial in TGCT that will generate preliminary data demonstrating the clinical utility of miR-371 in CS1 disease. CLIMATE will enrol CS1 patients recommended for active surveillance, test for miR-371 at predefined timepoints and correlate these findings with recurrence, leveraging prospectively collected clinical data within iTestis, a national testicular cancer registry.

Carole Harris: Using PBS data to understand pattern of care and survival in Australian patients treated for metastatic clear cell kidney cancer

Our study will describe how medications are used across Australia to treat advanced kidney cancer: which drugs, in which order and for how long. We will understand how long people live with these therapies and if there are sequences of treatment that appear to work better. This study has the advantage that it can look at how cancer therapies are used and how effective they are at a population level.

Our future aim will be to use this “linkage data” method as the backbone of real-world clinical trials, where ANZUP members in every hospital in Australia can take part, not just those of us lucky to be in hospitals with many research resources. Real world clinical trials make small changes in the way we use standard treatments, and can have big impacts to improve patients’ outcomes.
Craig Gedye: AdapTax
Feasibility, acceptability and safety of adaptively dosed docetaxel in men with metastatic castrate-resistant prostate cancer.

When prostate cancer spreads, injections that suppress the male hormone testosterone can control the cancer for some time, but it almost always starts to grow again later. These vulnerable and resistant cells of the cancer are often holding each other in balance; and when a treatment is used it can favour one group of cancer cells over another. This trial is designed to test the idea of taking a standard chemotherapy called docetaxel, and if it works to take breaks off the chemo, using it for long enough to control the cancer, but then stopping and saving it up until later to treat the cancer again (and again... and hopefully again, and again). While every man’s cancer is predicted to eventually become resistant to the chemo treatment, using an effective treatment more sparingly is hoped to spread the benefit over a longer period of time, without any more side-effects.

Kate Mahon: mGSTP1
A randomised trial of biomarker-driven intermittent docetaxel versus standard-of-care (SOC) docetaxel in metastatic castration-resistant prostate cancer (mCRPC).

In Australia last year, over 3,000 men died from prostate cancer and many more are living with this disease. Chemotherapy in the setting of prostate cancer which has spread to other parts of the body improves symptoms and survival, however, chemotherapy is associated with significant side effects. The standard way to deliver chemotherapy is to continue on a 3 weekly schedule while the cancer is still responding but this is often limited by an accumulation of side effects. Several small studies have suggested that some patients can safely have breaks in chemotherapy with less side effects and a better quality of life.

However, this is difficult to achieve with our current monitoring strategies. We have developed a new blood test which can accurately identify patients who are responding to chemotherapy. We plan to use this blood test to guide breaks in chemotherapy to provide more tolerable treatment and ultimately improve patients’ quality of life.

Shomik Sengupta: Genomic & immunological predictors of response to intravesical therapy
Many bladder cancers are treated with medications put into the bladder in order to prevent the cancers from growing further into the bladder wall. In some cases, these treatments do not work as they are meant to. At present, we do not know when the treatments might fail. The aim of this study is to assess bladder cancer samples to identify changes within them that may predict whether the commonly used treatments will work or not.
ANZUP’s History

2008   2009   2010   2011   2012   2013   2014

2008
ANZUP became a company limited by guarantee

2009
Awarded infrastructure funding from Cancer Australia

2010
Official launch of ANZUP in Sydney

2011
ANZUP Scientific Meeting held on the Gold Coast with COSA

2012
Phase II study of accelerated BEP (testicular cancer trial) reaches recruitment target

2013
Joint ANZUP/USANZ Scientific Meeting held in Melbourne

2014
First face to face Scientific Advisory Committee meeting

First Annual General Meeting

ANZUP Scientific Advisors Meeting in Melbourne with COSA

Joint ANZUP/USANZ Scientific Meeting held in Melbourne (renamed Masterclass in 2014)

First Trainee Day

ANZUP accrues highest number of participants outside UK for renal cancer trial (SORCE)

First stand-alone Annual Scientific Meeting (ASM) Sydney

ANZUP completes its first trial (EVERSUN) and presents results at ASCO GU

ANZUP leads global Enzalutamide trials

Launch of ANZUP ClinTrial Refer app

Inaugural Pedalthon fundraiser Sydney
ANZUP celebrates 10th anniversary year

ANZUP’s global ENZAMET trial reaches recruitment target of 1,100 patients

Sydney Pedalthon raises more than $1 million in four years

First full day Concept Development Workshops held for all disease-specific subcommittees

UNISoN (non-clear cell renal cell) and KEYPAD (clear cell renal cell) trials open to recruitment

ANZUP reaches 1,000 members

ANZUP PCFA’s partnership sees TheraP nuclear medicine advanced prostate cancer trial open to recruitment

Inaugural Melbourne Pedalthon

ANZUP reaches 1,300 members and is involved in 13 active trials

Hosted the first Asia Pacific Advanced Prostate Cancer Consensus Conference (APCCC) Satellite Symposium

395 delegates attend the ASM (July) – largest number of delegates to date

TIGER trial (germ cell) opens – August 2018

ANZUP and PCFA renew their memorandum of understanding to continue their collaboration on prostate cancer trials

TheraP trial reaches 50% recruitment

‘Is there a trial for me?’ campaign launched with Breast Cancer Trials Australia

ANZUP and PCFA announce new partnership to raise $1.5 million for prostate cancer trial

ANZUP celebrates 2015th anniversary year

ANZUP reaches 1,100 members

ENZAMET trial highlighted by ASCO’s annual report as a major advance in the progress against cancer

2nd Melbourne Pedalthon with 34 teams riding

BCGMM trial (bladder) recruits its 200th patient (13 March)

Below the Belt research Fund awarded to 18 projects

Concept development Workshops expanded to include 5th workshop – Quality of Life

TIGER trial (germ cell) opens – August 2018

ANZUP and PCFA renew their memorandum of understanding to continue their collaboration on prostate cancer trials

TheraP trial reaches 50% recruitment

‘Is there a trial for me?’ campaign launched with Breast Cancer Trials Australia

Launch of Below the Belt Research Fund

Inaugural ANZUP GU Preceptorship in Prostate Cancer

ANZUP reaches 2,000 members (12 March)

BCGMM trial (bladder) recruits its 200th patient (13 March)

Below the Belt research Fund awarded to 18 projects

Concept development Workshops expanded to include 5th workshop – Quality of Life

ENZAMET trial one of four ASCO Plenary Presentations

Inaugural 2019 Prostate Masterclass held in Boston

TheraP, UNISoN & Pain-Free TRUS B trials recruit their final patient

FDA approves enzalutamide for use with mHSPC in the US

Investigator meetings held for DASL-HiCaP, ENZA-p & #UPFrontPSMA trials
Mission, objectives, priorities

Our mission:
To conduct clinical trial research to improve treatment of bladder, kidney, penile, testicular and prostate cancer.

Goal 1
Continue to build on and develop high quality cutting edge clinical trials

ANZUP has a multidisciplinary membership base, those involved in the research and treatment of GU cancers, along with a body of individuals with personal experience of these cancers. This diverse panel ensures ANZUP develops robust, high quality clinical trial procedures. These trials are varied across each of the tumour streams ANZUP represents, and utilise diverse treatments including radionuclear medicine and online psychotherapy tools.

The Principal Investigators (PI) on many of the ANZUP trials have varied medical specialities including radiation oncologists and medical oncologists. It is an ongoing process to ensure the trial lead investigators come from varied disciplines, in efforts to have holistic input into the conducted research. ANZUP is also working to ensure junior researchers from all disciplines attend and contribute at workshops and events. Participation is encouraged by inviting junior researchers to our MDT Masterclasses, Prostate Preceptorship and Best of GU meetings. In addition, we have a Young investigator of the Year award which helps finance a junior researcher to attend an ANZUP and overseas meeting.

Regular analysis is undertaken by each subcommittee, as they report on current trials, trials in development and concepts submitted and in the pipeline at quarterly teleconferences.

All subcommittee members are encouraged to consider and submit new concepts through the established Concept Development Workshops that run across each of the five cancers ANZUP represents.

<table>
<thead>
<tr>
<th>Concept development</th>
<th>2017</th>
<th>2018/19</th>
<th>2019/20</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total workshops</td>
<td>4</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>Total attendees</td>
<td>98</td>
<td>115</td>
<td>43</td>
</tr>
<tr>
<td>Total concepts</td>
<td>22</td>
<td>32</td>
<td>229</td>
</tr>
</tbody>
</table>
Goal 2: Increase awareness, participation and access to ANZUP trials

ANZUP continues to increase awareness, participation and access to ANZUP trials through a variety of ways. Our subcommittee membership has continued to increase across all cancer types.

Regular attendees are asked to promote and encourage their colleagues and trainees to join and participate in the subcommittee meetings. Promotion of ANZUP also takes place at external meetings to highlight the benefits of ANZUP membership. This has been done at ANZUNS, the USANZ New Zealand Section Meeting, COSA and the Asia Pacific Prostate Cancer Conference.

ANZUP routinely invites rural members and their patients to provide content for the clinical newsletter UPdate and consumer magazine, ‘A little below the belt’. The magazine is distributed to more than 400 cancer centres, of which 28 are rural/regional.

ANZUP and the National Cancer Cooperative Clinical Trials Groups have provided funding for the Australasian Teletrial Model. This model was developed by the COSA Regional and Rural Group, and aims to use telehealth to improve access to clinical trials.

The model will not only benefit regional, rural and remote patients, but has the potential to connect centres within the same city to improve the access and recruitment to highly specialised clinical trials, including rare cancer trials. In response to COVID-19, telehealth has already expanded across Australia and New Zealand from March 2020, and ANZUP is embarking on its first tele-trial with the UNICAB trial.

The Consumer Advisory Panel (CAP) membership is reviewed annually to ensure the best mix of individuals on this panel. The CAP is involved across all ANZUP research activities including the Scientific Advisory Committee, subcommittee meetings, Concept Development Workshops and the Annual Scientific Meeting.

Community links have been further reinforced by inviting consumers to the Community Engagement Forum (CEF). The CEF is a free community forum that provides information and the opportunity to discuss the importance of clinical trials, raise the profile of ANZUP and the impact a diagnosis of ‘below the belt’ cancers can have on a person and their family. We also record these community forums to share beyond those who attended face-to-face.

Social media is another way ANZUP engages and educates the wider community on ANZUP activities and clinical trials. ANZUP has accounts for Twitter, Facebook, LinkedIn, YouTube and Instagram.

<table>
<thead>
<tr>
<th>Subcommittee</th>
<th>Total Members</th>
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</thead>
<tbody>
<tr>
<td>Prostate</td>
<td>442</td>
</tr>
<tr>
<td>BUP</td>
<td>302</td>
</tr>
<tr>
<td>Germ Cell</td>
<td>190</td>
</tr>
<tr>
<td>Renal</td>
<td>274</td>
</tr>
<tr>
<td>QoL</td>
<td>165</td>
</tr>
<tr>
<td>Translational</td>
<td>128</td>
</tr>
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Social Media Followers

<table>
<thead>
<tr>
<th>ANZUP Twitter followers @ANZUPtrials</th>
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<tbody>
<tr>
<td>1,666</td>
</tr>
<tr>
<td>2,065</td>
</tr>
<tr>
<td>2,384</td>
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<tr>
<td>2017/2018</td>
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<tr>
<td>2018/2019</td>
</tr>
<tr>
<td>2019/2020</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>ANZUP Facebook followers @ANZUPtrials</th>
</tr>
</thead>
<tbody>
<tr>
<td>1,927</td>
</tr>
<tr>
<td>1,979</td>
</tr>
<tr>
<td>2,234</td>
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<td>2017/2018</td>
</tr>
<tr>
<td>2018/2019</td>
</tr>
<tr>
<td>2019/2020</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ANZUP Instagram followers @ANZUPtrials</th>
</tr>
</thead>
<tbody>
<tr>
<td>192</td>
</tr>
<tr>
<td>510</td>
</tr>
<tr>
<td>450</td>
</tr>
<tr>
<td>2017/2018</td>
</tr>
<tr>
<td>2018/2019</td>
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<tr>
<td>2019/2020</td>
</tr>
</tbody>
</table>
ANZUP continues to review and develop its systems, procedures and governance principles to ensure we can deliver our strategic plan. The organisational structure of ANZUP reflects its corporate governance and operational areas of responsibility. The board, comprised of the Directors of the Company is responsible for financial management, corporate governance, reporting and compliance, and continual revision of organisational policy to ensure we develop a robust quality management system to deliver our strategic plan.

ANZUP’s Concept Development Workshops utilise templates to streamline the concept process. The templates for submission and concept review, along with the associated process, were refined in early 2017 by the SAC. We continue to liaise with our subcommittees and broader membership around tools that assist collaboration to build our capacity and capabilities.

With our expanding portfolio of studies and growing membership, clearly articulated delegation of duties and defined decision making processes are vital. ANZUP continues to recognise the importance of policies and documented processes to underpin the quality and integrity of our operations.

Fundraising continues to be an important element of ANZUP’s activities, enabling delivery on our strategic plan. In August 2019 a new position of Head of Partnerships and Engagement was created. This role will implement a three year fundraising plan to help grow sustainable, cost effective and regular revenue streams through fundraising. New key performance indicators will be set to help build the robust fundraising program for the future.

Our Below the Belt Research Fund ensures all the money raised through the Sydney and Melbourne Pedalthons is used to support research that is intended to lead future ANZUP trials. The Below the Belt Research Fund has to date raised over $1.75 million. ANZUP’s financial sustainability is also supported by the ASM. ANZUP continues to grow the ASM by developing and delivering a high quality scientific program. The meeting showcases ANZUP’s research activities and attracted 392 delegates in 2019.

| Goal | 3 |

Strengthen and build our capacity and capability to ensure we can deliver our strategic plan

<table>
<thead>
<tr>
<th></th>
<th>2016</th>
<th>2017</th>
<th>2018</th>
<th>2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>Delegates</td>
<td>297</td>
<td>335</td>
<td>395</td>
<td>392</td>
</tr>
<tr>
<td>International speakers</td>
<td>4</td>
<td>6</td>
<td>7</td>
<td>5</td>
</tr>
<tr>
<td>Submitted abstracts</td>
<td>57</td>
<td>78</td>
<td>53</td>
<td>73</td>
</tr>
<tr>
<td>Fellowships, scholarships and awards</td>
<td>40</td>
<td>47</td>
<td>42</td>
<td>39</td>
</tr>
</tbody>
</table>

FIRST QUALITY OF LIFE CONCEPT DEVELOPMENT WORKSHOP
Goal 4

Engage, collaborate and grow stakeholder relationships

ANZUP currently engages, collaborates and grows stakeholder relationships through a variety of means. Crucially, the renewed funding agreement with the Australian Government through the Cancer Australia Support for Clinical Trials supports ANZUP’s infrastructure.

ANZUP’s new supporter care initiatives will help build and retain engagement with volunteers, donors, philanthropists, corporate partners and other key stakeholders.

We also cannot function at our greatest capacity without the variety of collaborative links we have forged. This is exemplified by the four co-badged trials with other Cancer Cooperative Trials Groups (CCTGs) and our membership of the Executive Officers Network (EON) and Clinical Trials Consumer Network (CTCN). The EON provides a platform on which to share resources and ideas to build stronger links between groups while the CTCN shares information between the groups’ Consumer Advisory Panels (CAPs).

In 2019/20 ANZUP collaborated with the NHMRC Clinical Trials Centre (CTC) at the University of Sydney to conduct 11 clinical trials. ANZUP also collaborated with the Centre for Biostatistics and Clinical Trials (BaCT) to conduct 3 clinical trials. These long standing relationships ensure quality processes on trial development and operations.

Key Relationships

- Australia & New Zealand Urological Nurses Society (ANZUNS) - represented on the ANZUP SAC by Kath Schubach
- Australian Clinical Trials Alliance (ACTA)
- Cancer Australia
- Cancer Councils
- Clinical Oncology Society of Australia (COSA)
- Colleges (e.g. RACP, RANZCR, RACS)
- Kidney Health Australia
- Medical Oncology Group of Australia
- Movember
- National Cancer Cooperative Trials Groups
- Prostate Cancer Foundation Australia (PCFA)
- TROG (Trans Tasman Radiation Oncology Group)
- Cancer Research
- Urological Society of Australia & New Zealand (USANZ)

International Partnerships and Collaborations

- Alliance for Clinical Trials in Oncology
- Canadian Cancer Trials Group (CCTG)
- Cancer Research UK
- Cancer Trials Ireland (CTI)
- Children’s Oncology Group (COG)
- Dana-Farber Cancer Institute
- European Organisation for Research and Treatment of Cancer (EORTC)
- Medical Research Council (MRC) UK
- National Cancer Institute
- Prostate Cancer Clinical Trials Consortium (PCCTC)
- Prostate Cancer Foundation New Zealand (PCFNZ)
- University College London (UCL)

The most critical stakeholder relationship continues to be ANZUP’s multidisciplinary membership. For members, ANZUP provides an annual calendar of education and networking opportunities including the ASM, Concept Development Workshops, GU Preceptorship and the Best of GU evening symposium. ANZUP continues to support fellows, trainees and junior researchers through the facilitation of educational workshops and events, grant opportunities, scholarships, fellowships and awards that encourage the next generation of researchers to develop their skills, further explore their research areas, actively contribute to trial development and access experts in their field. The renewed agreement with PCFA to improve access to and funding for prostate cancer trials has cemented another key relationship.

Member communication is ongoing with regular email, print and social media updates. Staying in touch with the latest GU clinical trials research, networking and the opportunity to attend educational events are an important aspect of being an ANZUP member.
Goal 5

Increase engagement of the membership

ANZUP’s membership continues to grow and diversify, calling us to explore the ways in which we can aptly support and provide opportunities for our multidisciplinary membership. Crucially, ANZUP continues to develop communication strategies as tailored to the needs and interests of our members. This includes subcommittee participation, trial news, trial development, trial management and educational and fundraising events across various channels including email, print and social media updates.

The Concept Development Workshops, held across each of the major cancers ANZUP represents is another medium through which we support our membership. The workshops, facilitated by the chairs of each subcommittee, aid in the development of emerging clinical trial concepts transforming them into fully fledged clinical trials whilst providing a key educational and mentoring opportunity for members across each of the four tumour streams.

ANZUP is also active across a range of social media platforms, with profiles on Twitter, Facebook, LinkedIn, YouTube and Instagram. ANZUP’s Twitter account maintains a stronghold in terms of activity, with a highly engaged clinical following.

Other external communication strategies include the biannual publication of a consumer magazine, ‘A little below the belt’ which is distributed digitally and via print to Australian and New Zealand cancer centres, key stakeholders, donors, supporters and members. In addition we hold an annual Community Engagement Forum. This is free for the general public to attend and provides the community with information about clinical trials. The Below the Belt Pedalthon, now held in both Sydney and Melbourne, also raises community awareness of clinical trials, urogenital cancers and the Below the Belt Research Fund.

Opportunities to engage and communicate with corporate and philanthropic groups continue to be explored. ANZUP has established relationships with philanthropic and charity groups including the Paul Ramsay Foundation, Perpetual IMPACT Philanthropy, the Nordia Foundation, Roy Morgan Research Ltd, Ian Garrow, the Lin Huddleston Charitable Foundation, the Macquarie Group Foundation, PCFA and PCFNZ, Movember and the Melbourne Racing Club Foundation.

ANZUP utilises community and corporate databases to regularly communicate about the Below the Belt Pedalthon and other fundraising opportunities and events. Links have also been established with respected medical broadcasters and journalists to increase media coverage around ANZUP clinical trials, which we notably achieved with the announcement of the ENZAMET trial results at ASCO in June 2019.

“Excellent all round information regarding clinical trial research, their purpose, quality of life, nurse support and case studies regarding treatment choices and decision making”

Community Engagement Forum attendee feedback
ANZUP's profile has grown exponentially since our inception in 2008, on a local, national and international level.

The CAP plays a critical role in fostering increased community engagement and awareness of ANZUP and our clinical trial portfolio on both a local and national level. Significantly, ANZUP works alongside the CAP to gain a better understanding of the consumer perspective on clinical trials. ANZUP implements key strategies to involve and educate the wider community on clinical trial research and subsequent results. The CAP membership itself is reviewed annually to ensure there is an ideal mix of individuals on the panel. Trial information is easily available to the public via the ANZUP website, and is delivered in lay terms for accessibility.

‘Friends of ANZUP’ is another initiative developed by ANZUP, encouraging consumers where possible to receive regular updates on ANZUP activities. Through ‘Friends of ANZUP’, members receive a hardcopy of the consumer magazine, “A little below the belt”, as well as an invitation to the annual Community Engagement Forum.

The ANZUP website is a key point of reference to maintain our profile both amongst our current membership, and the wider community. The website is mobile-friendly, and frequently updated to ensure the most relevant information is accessible. There are features of the website for members-only, trials information for healthcare professionals as well as patients and carers, access to ANZUP publications, details of ANZUP’s events and awards as well as donor/supporter information. The website acts as the face of ANZUP – the first port of call for individuals seeking information on ANZUP activities, and as such is routinely maintained.

The Community Engagement Forum continues to build brand awareness as well as a deeper understanding of ANZUP activities. The free forum helps to maintain community links, held as an element of the ASM. The role of the forum is to provide the opportunity for an open discussion on the importance of clinical trials, to raise the ANZUP profile as well as discuss the lasting impact that a ‘below the belt’ cancer diagnosis can have on an individual and their family.

Celebrity endorsement is another means through which the ANZUP profile continues to be raised. The Rude Food campaign saw a plethora of internationally renowned chefs champion the ANZUP cause. Similarly, the Pedalthon continues to attract the support of high profile athletes including Kaarle McCulloch (who first became an ambassador in 2015).

The International Trials Steering Committee is an international relationship ANZUP continues to maintain. The committee provide scientific oversight of the conduct, analysis and reporting of internationally-involved trials - recommending, considering and reviewing proposed modifications to the study design protocol, reporting and analysis plan.

Internationally, the ANZUP ASM continues to attract a high-profile and impressive international faculty, specifically selected according to their skillsets and experience within ANZUP-represented cancers. Leading global clinicians speak, sharing their highly regarded views and experience with the Australian ANZUP audience. In 2019, 5 international speakers presented to over 400 delegates.
ANZUP’s ENZAMET Trial Takes Centre Stage

ANZUP’s ENZAMET trial certainly took the world by storm in 2019 – starting with findings being presented at the American Society of Clinical Oncology (ASCO) ASCO’s Annual Scientific Meeting in Chicago in June 2019 – and it didn’t stop there.

The ENZAMET trial began in 2014 and recruited 1125 patients from 83 medical centres around the world. Men with metastatic prostate cancer starting first-line ADT were enrolled in the study. The average age of the men in the study was 69 years; 11% of men had metastatic disease outside of the bones and lymph nodes.

ENZAMET (ANZUP 1304, NCT02446405, CCTG PR17) is a global collaborative investigator-initiated trial led by ANZUP and sponsored by the University of Sydney, in collaboration with the Canadian Cancer Trials Group, Dana-Farber Cancer Institute, and Cancer Trials Ireland (enrolling patients from Ireland and the United Kingdom). The University of Sydney NHMRC Clinical Trials Centre provided central study coordination.

Astellas Pharma provided drug and financial support but was not involved in study conduct or data analysis.

ENZAMET results presented at ASCO

On 2 June 2019 findings from the ENZAMET trial, led by ANZUP, were presented by Professor Christopher Sweeney at ASCO’s Plenary session at their Annual Meeting in Chicago. The ENZAMET trial was chosen as one of only four plenary sessions from over 6,200 abstracts received – a remarkable achievement. The ANZUP-led trial showed a 33% improvement in overall survival and a 60% improvement in progression-free survival, for men with metastatic hormone sensitive prostate cancer who received enzalutamide in addition to standard of care therapy (androgen deprivation therapy, ADT), with or without docetaxel chemotherapy.

The results were also simultaneously published in the New England Journal of Medicine.

The positive findings from the ENZAMET trial will mean that once enzalutamide is available, men with metastatic prostate cancer will have another treatment option.

The interest in the trial results was felt worldwide – with news, online and print coverage from around the world - from Channel Nine News in Australia, to France, Japan, Mexico, Ireland, USA, United Kingdom and everywhere in-between. It certainly has been a whirlwind ride for ANZUP, and one that shows no sign of stopping quite yet!
Enzalutamide receives U.S. FDA approval for treatment of men with metastatic hormone-sensitive prostate cancer (mHSPC)

In December 2019, enzalutamide (XTANDI™), was approved by the U.S. Food and Drug Administration (FDA) for men with mHSPC. Enzalutamide is a current standard of care in hormone-resistant prostate cancer and this approval helps make the drug available to men in the U.S. earlier in their cancer course. The ENZAMET trial provided valuable clinical information documenting the overall survival benefit when enzalutamide is used in the mHSPC setting.

“Through the ENZAMET trial we discovered that adding enzalutamide to testosterone suppression in men with mHSPC can give much better cancer control and longer survival,” said Professor Christopher Sweeney.

“This is true both for patients with high burden of disease, with multiple bone metastases or liver metastases, as well as men with a lower burden of disease. The new treatment option is especially relevant for men who cannot tolerate chemotherapy and have a lower burden of disease.”

“This is a step forward and another option for men with mHSPC, although enzalutamide is not yet approved or reimbursed in Australia in this setting,” says Professor Ian Davis.

ANZUP’s ENZAMET trial results recognised as one of the most important clinical research advances of the past year

On World Cancer Day, Tuesday 4 February, the American Society of Clinical Oncology, Inc. (ASCO) released its Clinical Cancer Advances 2020: ASCO’s Annual Report on Progress Against Cancer. This report highlights the most important clinical research advances of the past year and identifies priority areas where ASCO believes research efforts should be focused moving forward.

ANZUP’s ENZAMET study, “Enzalutamide with Standard First-Line Therapy in Metastatic Prostate Cancer,” was selected for inclusion in this year’s edition.

ANZUP Chair Professor Ian Davis, said metastatic prostate cancer was still the second-leading cause of cancer death in Australian men after lung cancer.

“The benefits of enzalutamide had already been established for prostate cancers that are no longer responding to hormonal therapy. ENZAMET showed that adding enzalutamide to standard treatment for men starting hormonal therapy for prostate cancer led to 33% reduction in the chance of dying of prostate cancer, and a 60% improvement in the time it takes to detect the cancer growing again. These results were much better than we thought they might be when we started the trial.

“Prostate cancer is complex and so are the benefits, side effects and risks of multiple treatments.

“Clinical trials are the most effective way of determining which treatments, alone or in combination, will provide the greatest survival benefit to the patient with the least adverse outcomes.”

Professor Christopher Sweeney, co-chair with Professor Ian Davis of the ENZAMET trial, said, “Inclusion in ASCO’s Annual Report is testament to the fact that this is one of the most significant findings yet in clinical trials for men with metastatic hormone-sensitive prostate cancer – and a great example of effective international collaboration.”

The ENZAMET project has been a great example of academic research: identification of an important clinical question leading to a carefully performed clinical trial, and outcomes that were always going to be informative whatever the result. We have also been able to generate a global network of clinicians, researchers, and coordinating centres, which will not only support the ongoing work for ENZAMET but that will push ahead with the next set of questions.

Professor Ian Davis, ANZUP Chair, ENZAMET Co-Chair
It is great to see that ENZAMET has helped the field make another step forward in improving the outcomes of prostate cancer. However, this is just the end of “Chapter 1”. I am excited to start on the next chapter with everyone as we define the quality of life, health economic and long term benefits. And then the biological studies will be another page turning chapter. It is such an honor to be writing this “good book” with all the ENZAMET investigators. Remember too, the ENZARAD book is also being drafted...

Professor Christopher Sweeney
ENZAMET Co-Chair
ENZAMET Media Coverage

**3+ MILLION**
FACEBOOK REACH

**5+ MILLION**
TV/ONLINE VIDEO REACH

**8.9+ MILLION**
TWITTER IMPACTS

**10+ MILLION**
ONLINE NEWS REACH

Proud to see our @ANZUPtrials #ENZAMET study highlighted by @ASCO annual report as a major advance in the progress against cancer.

@Prof_JanD @ChrisSweeney1 @TrialsCentre @cancertrials ie @ONCancerTrials @CancerAustralia auwlyt1hNC50U3uB
Scientific Advisory Committee: Ian Davis and Martin Stockler

The ANZUP Scientific Advisory Committee (SAC) provides overall scientific oversight of ANZUP’s activities. It was established and is constituted to ensure that ANZUP receives strategic guidance from a broad and diverse range of disciplines, crafts, and individuals. The SAC coordinates, reviews, and prioritises research ideas through their development for ideas through to concepts and on to mature proposals and finally full research initiatives. It does so under the guidance of the ANZUP Strategic Plan 2018-2020, and provides advice to the Board to help it make strategic and operational decisions to enable those initiatives to be achieved. Meetings of the SAC allow for input and “horizon scanning” across the areas of clinical need and emerging science, to help inform development of ideas that will remain relevant to the wider community even after several years of trial conduct and analysis. The SAC is also a mechanism through which ANZUP can communicate with the various stakeholder groups and organisations represented by the SAC membership. This helps ANZUP move towards its goal of improving outcomes by generation of new evidence, and implementation of those research findings in the clinical and wider community through changes in health care policy and practice.

The ANZUP Strategic Plan 2018-2020 is due for renewal. A component of that process will involve input from the SAC, to help ensure that appropriate scientific direction is included, together with multidisciplinary inclusiveness and broad applicability and relevance of what we do. We will continue to look for areas of unmet clinical need, gaps in knowledge, emerging scientific evidence, opportunities to work creatively together, ways to involve ANZUP and the wider community more effectively, and investigate new models of care and of research that will open up further directions to pursue. The SAC agenda has increasingly moved away from a reporting and specific oversight role, functions now largely delegated to specific Trial Management Committees; to more robust and engaging processes of strategic development.

Membership of the SAC is reviewed annually by the Board in the light of recommendations from the various professional bodies or special societies represented in its composition. All ANZUP members are welcome and invited to participate in ANZUP’s broader scientific processes, such as subcommittees, workshops, educational and training events, career development initiatives, and participation in our Annual Scientific Meeting. We are also open to suggestions on how to improve our systems, structures, and processes even further.
Bladder, Urothelial and Penile Cancer (BUP) Subcommittee: Dickon Hayne and Shomik Sengupta

We have now had 12 months to settle into the renamed subcommittee - and we have definitely focussed on bladder, urothelial and penile cancer over the past year.

Starting in March 2020, we saw significant changes made by institutions so they can manage COVID-19. This has and will continue to have an impact on usual trial operations - but some Bladder, Urothelial and Penile cancer trials were progressing pre-pandemic and have continued to do so. Below is an update on BUP committee activity and additional developments.

Currently recruiting ANZUP trials

**BCGMM**

The BCG-mitomycin study, comparing sequential BCG & mitomycin to standard BCG for high-risk non-muscle invasive bladder cancer (NMIBC), has recruited steadily and has 264 patients of a planned 500 patients accrued. The UK site and two more sites in Australia are to open in the coming year.

Global BCG and mitomycin shortages continued throughout the year, causing numerous problems and making the management of patients very difficult.

**PCR MIB**

The PCR-MIB study was temporarily suspended in March 2020. Up until that point, the 21st patient (of 30) was screened and recruited to the study.

An interim analysis was conducted that showed no new safety concerns and an abstract was submitted to GU ASCO based on pre-designed stopping rules.

Potential future studies update

**ACCEPT**

ACCEPT multicentre cystectomy database is collecting data from West Australian centres, with ethics and governance review underway to open at other sites interstate. It is hoped this database will not only provide a much-needed audit of cystectomy practices but also enable implementation and evaluation of interventions such as Enhanced Recovery pathways.

The South Metro Health Service Human Research Ethics Committee (HREC) in WA is now the lead HREC for the national mutual acceptance process. Therefore, all public hospitals now have ethics approval. Each site will require governance approval.

Due to the low-risk nature of the study, waiver of consent has been obtained for retrospective and prospective data collection (rather than the opt-out consent previously required). In addition, the entire ethics approval process was completely re-done by Cynthia Hawks from Fiona Stanley Hospital. This will mean it becomes easier to open centres and result in a large, multi-centre audit.

**NMIBC**

Developing a Patient-Reported Symptom Index for Non-muscle Invasive Bladder Cancer.

Water irrigation for low/intermediate risk (non-muscle invasive bladder cancer), NMIBC, is a Below the Belt funded single centre pilot study, with plans for a subsequent ANZUP trial to compare it to post-resection chemotherapy. Currently, patients are being enrolled on a 30-patient, single-arm pilot ‘WATIP’ study. Patients are given a trans-urethral resection of bladder tumour (TURBT) or bladder endoscopic treatment followed by 3 hours of post-operative water irrigation.

As at 31 March 2020, 20 patients out of a total of 30 patients have been recruited. Elective surgery was impacted by COVID-19 so it is hoped the remaining 10 patients will accrue over the next 3-6 months.

So far the procedure has been feasible and no safety issues have been found. Samples have been collected from study patients together with samples from standard saline-irrigated patients. At each time point it has been found there are fewer numbers of viable cells in the water-irrigated samples compared to the saline-irrigated cells.

A grant application for a randomised trial was unsuccessful last year, however the application is being amended to include this latest data and will be resubmitted in 2020.

**Exercyst**

The Exercyst trial is titled - Exercise Medicine Prior to Open Radical Cystectomy: Feasibility and Preliminary Efficacy. To date 14/20 patients have been recruited to this single-arm exercise study and 10 patients have completed the study. Recruitment should hopefully be completed by the end of 2020. The study is progressing well.

In addition, Exercyst 2 is being developed. It will be a post-operative exercise trial with dose escalations, looking at the feasibility and safety of immediate post-operative exercise after major abdominal surgery.
Over the past year the Renal Cell Subcommittee has continued to work towards the mission of improving treatments and outcomes for patients of kidney cancer. The year has been challenging, productive, rewarding with going activity, developments and the progression of renal cell trials.

The UNISoN study continued to recruit extremely well over the past 12 months. It now has only a few patients remaining on part one of the trial who are soon to transition to part two. Yet again we are very grateful to the teams working on this study around Australia.

The KeyPAD study continues to recruit, but recruitment has been slow. The incidence of RCC classified as IMDC favourable risk appears to be decreasing in Australia, and most patients have intermediate or poor risk RCC. We are now contacting referring doctors at KEYPAD sites to cross-refer patients. In addition, the possibility of opening the study in New Zealand is being explored as well as a radical change in protocol to include a new cohort of patients.

New trials also continue to thrive, with the UNICAB study – developed by Dr. David Pook and Dr. Carol Harris alongside ANZUP and BaCT. The UNICAB study aims to test the efficacy of cabozantinib in those who have taken immune checkpoint inhibitors for non-clear cell kidney cancer, and we eagerly anticipate the results of this trial.

The UNICAB study opened across 11 sites in Australia with a target of 48 participants. This study is an exciting phase II trial of cabozantinib in patients with metastatic or unresectable non clear-cell renal cell carcinoma who have progressed on, or are not candidates for immunotherapy. UNICAB was designed as a partner to the UNISoN study, as patients can be enrolled on UNICAB if they progress on UNISoN. The study also provides a treatment option for patients who have medical conditions that do not allow them to be treated with immunotherapy. In addition, UNICAB is being extended as a tele-trial model at Border Medical Oncology. ANZUP will be the first Cooperative Trials Group running a trial by telehealth.

As we look ahead we have high expectations for another successful, busy year, hopefully without the challenges presented by the COVID-19 pandemic. We look forward to the growth of renal cell trials, and another productive year for the Renal Cell Cancer Subcommittee. Plans for future studies continue and we would like to thank all the RCC subcommittee members, our clinical trial sites, our NHMRC Clinical Trials Centre collaborators, and most importantly, all trial participants.

Renal Cell Cancer Subcommittee: David Pook and Craig Gedye

Over the past year the Renal Cell Subcommittee has continued to work towards the mission of improving treatments and outcomes for patients of kidney cancer. The year has been challenging, productive, rewarding with going activity, developments and the progression of renal cell trials.

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Concept Development Workshops

The Concept Development Workshops (CDW) are now an integral component of new trials development. They give members a unique opportunity to present new concepts, participate in robust discussion around gaps in research and plan for future grant applications.

Our BUP Concept Development Workshop was held in Sydney in April 2019 with over 20 attendees and 5 concepts presented.

The BUP Committee looks forward to further progression of concepts and trials. We would like to thank all BUP committee members, trial centres and collaborators, and most importantly the trial participants. We look forward to another productive year – hopefully without any unexpected hurdles.

SUBDUE-1

The 2019 Below the Belt grants included funding for a Phase I study of sub-urothelial injection of durvalumab (SUBDUE-1). The study is open and was recruiting within 12 months of the initial idea for the concept being formulated. Two patients have been recruited thus far.

This trial looks at feasibility and toxicity of a sub-urothelial injection of durvalumab as a potential new primary treatment for non-muscle invasive bladder cancer. The trial recruits patients already scheduled for cystectomy and involves administration of the drug into the bladder wall with a dose escalation protocol.

ANZUP has been heavily involved in the development of the study, which is running only at Fiona Stanley Hospital and is sponsored by South Metro Health Services. AstraZeneca is providing durvalumab but no other support for the study. The trial is funded by a Below the Belt grant and another local grant (Spinnaker) in WA has been obtained for translational work.

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RESEARCH HIGHLIGHTS

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Prostate Cancer Subcommittee: Scott Williams and Lisa Horvath

Exciting achievements and new studies over the past 12 months have helped ensure ANZUP remains a well-recognised co-operative group in prostate cancer clinical trial research. The Prostate Cancer Subcommittee continues to grow even with the challenges faced due to the COVID-19 pandemic. ANZUP has remained committed to running the prostate cancer trials and can report on trial developments and achievements.

ENZAMET

ANZUP’s ENZAMET trial certainly took centre stage this year.

In June we celebrated a major achievement with ENZAMET featuring as a Plenary Session at the 2019 American Society of Clinical Oncology (ASCO) Annual Meeting. Congratulations to Study Co-Chairs ANZUP Chair Prof. Ian Davis and Prof. Christopher Sweeney who presented the results at ASCO.

The results generated much media and social media interest and certainly put ANZUP on centre stage.

It didn’t stop there; in December enzalutamide received U.S. FDA approval for treatment of men with metastatic hormone-sensitive prostate cancer, and on 4 February 2020 on World Cancer Day ASCO released its Clinical Cancer Advances 2020: ASCO’s Annual Report on Progress Against Cancer, and our ENZAMET study was selected for inclusion in this year’s edition. You can read more about ENZAMET on page 28 in this report.

In addition, an International Trials Steering Committee has been established for ENZAMET (as well as ENZARAD) translational studies on the large bioresource associated with these studies. This includes representatives from all regions with specific expertise. The Committee meets formally every six months via teleconference. A sub-group of four experts meets monthly to prioritise proposals for the use of specimens. Detailed proposals with budgets are currently being finalised for submission for funding.

TheraP

Accrual completed for the initial analysis of TheraP, the randomised trial of cabazitaxel chemotherapy against 177Lutetium-PSMA in castrate-resistant disease. An abstract related to early exciting results was submitted to ASCO 2020, for their virtual meeting in May. Again, this trial has amassed substantial national and international interest, showcasing the strength of Australian research teams in the global sphere of clinical trial research.

ProPSMA

The primary analysis for the ProPSMA study, (co-badge with ARTnet and TROG) has been completed. This study had been booked for a Plenary Session at the EAU in Amsterdam, however the EAU was cancelled due to COVID-19. It was published in the Lancet on 21 March and will be another headline study for Australia in the PSMA space.

Pain-Free TRUS B

The Pain-Free TRUS B randomised trial completed accrual and this study has an instantaneous endpoint. A recruitment total of 420 patients was achieved following ongoing contributions from our NZ study leaders. The analysis plan is now being discussed.

Upcoming studies – due to open in the 2020/2021 reporting period

DASL-HiCaP

DASL-HiCaP is an ANZUP-led randomised phase 3 trial adding darolutamide to androgen deprivation therapy and definitive or salvage radiation in high risk, clinically localised prostate cancer. Study Co-Chairs Associate Professor Tamim Niazi and Professor Christopher Sweeney are excited with the potential this trial has for patients.

ENZA-p

ENZA-p is an ANZUP-led randomised phase II trial using PSMA as a therapeutic agent and prognostic indicator in men with metastatic castrate-resistant prostate cancer treated with enzalutamide. This study is being led by Associate Professor Louise Emmett from St Vincent’s Hospital in Sydney. The study aims to recruit 160 patients, across 12 sites – with the view to open the study by mid-2020. Initially 10 sites (which have been used for TheraP) are planned to be opened for this study.
#UpFrontPSMA

#UpFrontPSMA is a Randomised Phase 2 Study of Sequential $^{177}$Lu-PSMA617 and Docetaxel Versus Docetaxel in Metastatic Hormone-Naive Prostate Cancer. Study Co-Chairs are A/Prof. Arun Azad and Prof. Michael Hofman from the Peter MacCallum Cancer Centre. This study will be run at sites that participated in ENZA-p and will be co-badged by ANZUP and VCCC/ the Peter MacCallum Cancer Centre.

Concepts

With the renewal of our Memorandum of Understanding for our PCFA ANZUP Partnership Grant for a further three years, ANZUP called for prostate cancer concepts late in 2019.

A number of high quality concepts were submitted and the shortlisted applicants presented their concepts to a multidisciplinary panel on Tuesday 26 November 2019. Many creative and interesting concepts were reviewed and discussed.

The next ANZUP PCFA sponsored protocol was awarded to Shahneen Sandhu for her novel concept: Lutetium-PSMA with ipilimumab and nivolumab in metastatic hormone naive prostate cancer (mHNPC).

Exciting achievements and new studies continue to make sure ANZUP is well-recognised in prostate cancer clinical trial research. We look forward to another busy and successful year ahead – hopefully with less social distancing and COVID-19 challenges! We extend our thanks to the Prostate Cancer Subcommittee for their commitment and enthusiasm to improving treatments and outcomes in prostate cancer.

Germ Cell Cancer Subcommittee: Ben Tran and Fritha Hanning

The Germ Cell Subcommittee has again been very busy welcoming new members who have contributed to research activity, including trainees. The focus for the past 12 months was to proceed with a surgical study (currently in protocol finalisation) and also secure funding for a study examining the role of miR-371 in clinical stage 1 disease and tools to address fear of cancer recurrence.

Highlights of the year in review for the Germ Cell Subcommittee include:

**TIGER**

Globally, this is a very important study with potential to change practice. It is pleasing to have TIGER open at multiple sites in Australia. We have now recruited 5 Australian patients and sites continue to work hard to identify suitable patients. TIGER compares TIP versus TICE (high dose with stem cell rescue) as first salvage for platinum refractory disease.

**iTestis**

iTestis continues to expand, opening at multiple sites across the country. iTestis now holds data on over 200 testicular cancer patients. In order to provide a true representation of testis cancer treatment and outcomes across the country, we need to engage additional sites from all states and territories. iTestis is Australia’s testicular cancer registry. It has a user friendly web-based interface and facilitates prospective collection of high quality clinical data. iTestis has received ANZUP Below the Belt funding and launched in late 2018. Understanding how we treat testicular cancer in Australia will help improve outcomes for all patients. Additionally, having iTestis as a robust data collection tool will facilitate registry based trials to examine new questions aimed at helping patients live better lives.
P3BEP

P3BEP continued to recruit well over the past year. 119 patients have now been recruited across ANZ, UK and COG sites. A/Prof Peter Grimison continues to be the driving force behind this important Australian-led, international, 2-stage open-label randomised phase 3 trial study which will determine if accelerated BEP is more effective than standard BEP as first-line chemotherapy for men, women and children with intermediate- or poor-prognosis advanced GCTs.

In the pipeline

Over the past year, the team has worked hard to get these projects up and running:

1) PERMEATE is a clinical trial with the dual objectives of defining a role of miR-371 in stage 1 testicular cancer and using a novel tool to address fear of cancer recurrence in this patient cohort. Ben Tran leads an ANZUP MRFF grant, submitted in Feb 2020, which will serve as a parallel study to both SWOG 1824 and AGCT1531, two international studies which have only recently started recruiting patients. We all eagerly await the outcome of this submission.

2) PRESTIGE is a single arm surgical cohort study examining the impact of primary RPLND for stage 2 seminoma and non-seminoma on health related quality of life. As the focus on survivorship in testicular cancer has increased, the need to minimise treatment related toxicities has become apparent. As such, there is a renewed shift towards primary RPLND as opposed to chemotherapy or radiotherapy for selected patients with stage 2 seminoma and non-seminoma. As studies examining this continue to recruit globally, there is a knowledge gap which needs to be addressed, that being the impact of such surgery on quality of life. PRESTIGE aims to fill this gap by describing the impact of RPLND on short and long term HRQoL, in particular, its impact on sexual function.

3) An ANZUP survivorship care plan is being developed to help testicular cancer patients live normal healthy lives after completing their treatment. Jeremy Lewin has led a herculean effort to generate a document which is relevant across Australia and NZ. We look forward to having this available to all our patients.

4) Hypogonadism is a complex issue in testicular cancer survivors and is generally divided into primary and secondary causes. Secondary causes are under-appreciated, being a consequence of being overweight and therefore potentially more common in today's society. Feasibility studies using iTestis are underway to determine the true proportion of secondary hypogonadism in testicular cancer survivors.

International collaborations

Through TIGER and P3BEP, the ANZUP germ cell subcommittee continues to foster strong international links. Additionally, other translational projects and future clinical trial planning continue to build upon this. The global academic germ cell community is a dedicated and passionate group of clinicians. We all work closely together with the aim of improving the lives of these young men. ANZUP has contributed to updates in the International Germ Cell Cancer Group Prognostic classification 2.0, and continues to be intimately involved in the Movember led Global Action Plan -5 focused on identifying biomarkers of platinum resistance. The past year has been productive and challenging in ways we did not expect. We would like to thank the enduring hard work, talent and dedication of the sub-committee members and trials teams who have remained focussed and continue to help us improve outcomes for patients with germ cell cancer.
As for so many of us, it has been a year of challenges, change and adaptation – but despite this the Quality of Life (QoL) and Supportive Care Subcommittee has had another industrious year. After a productive 2019, the first quarter of 2020 saw us transition rapidly to online care, teaching, meetings, and socialising, but progress continued to be made on projects falling under the remit of this committee.

Concept Development Workshops (CDWs)

The QoL subcommittee members have been committed to attending the tumour site subcommittee meetings and the CDWs on a regular basis over the past 12 months. Early input and engagement from those of us with a supportive care, psychosocial, and quality of life focus is critical to maximising the outcomes of ANZUP Clinical Trials. The aim of QoL involvement in each tumour site subcommittee meeting is to draw a Supportive Care and QoL perspective into each project, facilitating inclusion of nursing, supportive care, and QoL questions and substudies into ANZUP trials.

In addition to quality of life outcomes, we are assessing fear of cancer recurrence or anxiety and depression in other clinical trials. We are seeing an increase in discussion of patient experience during CDWs, the times at which data can best be collected as part of routine follow-up in a trial, and the requirement to include qualitative substudies to inform thinking about the problem and experience. This is exciting as it means we will be better placed in the future to assess for these concerns, develop and evaluate interventions, and even investigate implementation of evidence-based approaches within ANZUP’s clinical trials. We have also, with Richard De Abreu Lourenço, been working on the inclusion of preference assessments within a number of trials. This will help direct resource as needed to the psychosocial and supportive care needs that patients identify as part of their treatment decision-making.

ANZUP ASM 2019

Natasha Roberts reported preliminary results of her Janssen Fellowship at the Nurses Symposium. She is investigating patient experiences when participating in ANZUP clinical trials which will influence how we approach and support those taking part.

Gay Corbett presented her work on developing resources to support patients experiencing psychosexual challenges after a cancer diagnosis. This is work developed through the concept development workshops following participation in March 2018.

Sonia Stratchen presented the work she led to implement a care plan for men on androgen deprivation in her region at the ASM Supportive Care Breakfast. The presentation stressed that the implementation of innovations in to practice requires substantial effort, dedicated time, and engagement of all stakeholders. There was a significant level of discussion about how to implement this care plan across the country.

Best of GU November 2019

The Deputy Chair, Associate Professor Catherine Paterson travelled to Adelaide to be part of ANZUP’s Best of GU. Catherine gave an overview of the work she has undertaken to identify the unmet needs of men with uro-genital cancers. A large portion of her focus has been in the area of penile cancer, a long neglected and challenging rare cancer, where there is plenty of work to be done.

Presentations from members at COSA November 2019

Several poster presentations from QoL subcommittee members were given at the Clinical Oncology Society Meeting (COSA) in Adelaide in November 2019.

Natasha Roberts again presented the preliminary results of her qualitative study exploring patient experiences of participating in clinical trials. One of the key findings is that patients felt they take part in trials but don’t get to hear more about their progress and outcomes. These findings have led us to work with ANZUP’s Consumer Advisory Panel to develop innovative ways to improve patient experience.

Tam Bui gave a presentation based on survey results – ‘Experiences of genitourinary cancer nurses with scanxiety and tumour marker-related anxiety in people with cancer: results of a survey’. A manuscript reporting the results of this survey has been drafted and will be submitted for publication.
Nicholas Ralph gave a presentation on the 10-year quality of life outcomes in men with prostate cancer. Using the results from 106 men recruited pre-treatment, three trajectories were identified - HRQOL (physical, mental, and life satisfaction). It was found ADT, comorbidities, and lower socioeconomic status indicates risk for poorer long-term quality of life. The question now, is how to support men at risk of poorer HRQOL to ensure they remain as well as possible for as long as possible.

New study: Online exercise for people with metastatic prostate cancer

Holly Evans, Camille Short and team launched an online exercise study for individuals with metastatic prostate cancer. The 8-week program involves an individually tailored exercise program, devised using an online algorithm. It also includes complementary education and telehealth support for participants.

So, as we emerge from the COVID-19 pandemic we will need to see how best to transform our models of care to keep what works from both telehealth and face-to-face care to deliver better person-centred care. In addition, the QoL subcommittee will continue to focus their energy on where the greatest contribution to ANZUP can be made. I look forward to another productive year ahead, in which we can continue to improve outcomes for the patients impacted by GU cancers.

Noel Castan Fellowship in Quality of Life

We are incredibly grateful to Anita Castan for her generosity in establishing this fellowship in her husband’s name. The initial Fellowship was awarded to Kath Schubach, a long-standing and active member of the QOL and Supportive Care Subcommittee, to expand the analysis of QOL data already collected as part of ANZUP trials. In carrying out this work Kath will be building our knowledge about the impact of GU cancers on individuals diagnosed with it and directing our attention to gaps in care that need to be filled with evidence-based interventions.

Translational Subcommitteee: Arun Azad and Anthony Joshua

The year has proven to be another busy and productive one for the Translational Research Subcommittee, with a number of exciting highlights and important updates.

The Translational Research Symposium in July in Brisbane, part of the ANZUP Annual Scientific Meeting (ASM), was very successful and well attended. Our international speakers Betsy Plimack and Phuoc Tran gave outstanding talks and were ably complemented by our line-up of local speakers including Niall Corcoran, Ben Tran, Mitchell Lawrence, Ian Vela, Lisa Horvath and Lisa Butler. We extend our thanks to all our speakers for another fantastic Symposium and we look forward to once again showcasing the best of our translational research at the next ANZUP ASM.

The ENZAMET/ENZARAD Translational Research Steering Committee has overseen the selection of several key projects using correlative samples from ENZAMET. Thanks goes to the independent group that reviewed and prioritised proposals. The projects that will go forward will utilise cutting-edge technology to deliver critical correlative data from this pivotal, practice-changing trial. We are also very pleased that these translational studies will bring together a team of researchers from across the globe. Enhancing links with international translational researchers has been a key goal of the Translational Research Subcommittee and we are delighted that ENZAMET is providing a platform to achieve this. Although laboratory research is our major focus, there are additional opportunities to perform sub-studies using data from ENZAMET. One example is an imaging study led by Associate Professor Anthony Joshua that will correlate PSMA PET data with clinical outcomes.

While pushing forward with the planning for ENZAMET translational studies, we will also shortly commence planning for correlative samples collected for TheraP. We eagerly await the chance to commence translational research from this exciting study.

Bio-specimen collection continues as part of existing trials, including BCGMM, P3BEP, KEYPAD, UNISoN and PCR-MIB. As always, we are grateful for the patients and families who enrol on our trials and donate bio-specimens that underpin our translational research. We could not conduct our activities without these high-quality samples, and acknowledge the participating sites diligence in obtaining correlative samples from our ANZUP trials.

Moving forward, the Translational Research Subcommittee hopes to play a pivotal role in the development of new clinical trials with a primary translational endpoint, and we also look forward to another successful year ahead.
ANZUP’s approach to all of its clinical trials is to centre the research question on its value to the community. The ANZUP Consumer Advisory Panel (CAP) are people who have either had a cancer diagnosis or have cared for a family member/loved one, and have a demonstrated commitment to clinical trials research as a key strategy for improving the outcomes of those affected by genitourinary cancers. It is with great pleasure that I provide this 2020 Annual Report on behalf of the CAP.

Highlights of the year in review

• We welcomed two new CAP members Melissa Le Mesurier and Michael Twycross to the team as Bladder Cancer Representatives. They attended the 2019 ASM to meet other CAP members and gain a better understanding about ANZUP and how the CAP interacts with the membership. We are delighted to have them on board.

• Attending the 2019 ASM to make connections is a mainstay of the CAP calendar. We had a half day face to face education session with excellent presentations from Ian Davis, Leonie Young, Scott Williams, Ben Tran, Jaclyn Verghis and Nima Amatya. Lucy Byers and Marg Mc Jannett facilitated our final session with a group discussion on what the CAP can do to assist in promoting clinical trial research in the community. A significant outcome being the dissemination of ANZUP’s consumer magazine A little below the belt to the Cancer Centres and GP offices across ANZ.

• We actively participate in the main scientific program and CAP member Michael Tywcross represented the CAP in the bike ride challenge at the ASM dinner.

• We were able to raise awareness within the general community of the importance of considering clinical trials as part of a treatment program by taking part in the Community Engagement Forum. The CAP members chaired and presented at this forum.

• Ray Allen (Deputy Chair) was invited to join a Survivorship Essentials Expert Panel, with the Prostate Cancer Foundation of Australia for a project aimed at identifying and prioritising the needs of prostate cancer survivors, with the added overlay of practical implementation.

• We had CAP representation at the ANZUP/PCFA Partnership Grant Concept Workshop held in November 2019 with Ray Allen also attending a protocol development meeting to discuss Shahneen Sandhu’s concept that was selected for the grant: Lutetium PSMA with ipilimumab and nivolumab in metastatic hormone naive prostate Cancer (mHNPC).

• I attended the 2019 ASCO meeting in Chicago on a patient advocate scholarship. The highlight of attendance was being present at the Plenary session with a large contingent of ANZUP members and supporters. Here Chris Sweeney presented the positive results of the ENZAMET study. The CAP had reviewed the ENZAMET patient information and consent forms back in 2014, and the results of this trial is what we had always hoped to see.

Other key activities in 2019/20 include:

The CAP had the opportunity to review Patient Information and Consent Forms for:

- SUBDUE
- #UpFrontPSMA
- DASL-HiCaP
- ENZA-p

• CAP members were appointed as Associate Investigators for two studies. Matt Leonard on the PERMEATE testicular cancer trial and Belinda Jago on the ENZAMET biomarker cohort study.

• CAP members assisted with a grant application to pursue the next step of the CAP project aimed at raising awareness of clinical trials. This will follow on from the successful clinical trials video jointly produced with Breast Cancer Trials. This is in line with ANZUP’s strategy to increase engagement with consumers, carers and the broader community to promote the importance of clinical trial research in GU Cancers. We will find out later in 2020 if ANZUP has been successful.
• CAP members have also participated in recent CREST Health Economics for Consumers and a recent QOL seminar.

• We continue to have an active involvement in Concept Development Workshops, disease specific sub committees, the review panels for the BTB Research Fund, the Mundipharma Fellowship, Astellas Young Investigators Award, and the Nursing and Allied Health awards, Trial Management Committees and a number of ad hoc requests by ANZUP members requiring consumer comments.

• We are willing supporters and contributors to ANZUP’s consumer magazine ‘A little below the belt’ and the Sydney and Melbourne Pedalthons.

In closing the CAP report for this year, the last quarter has certainly seen some big changes with the arrival of COVID-19. In the ANZUP clinical trials space its activities have created a flurry of activity while we considered what needed to change quickly to ensure the safety of patients, health workers and employees. While we will miss our face to face interactions, some positive outcomes have been the better and more efficient use of our time through video conferencing and less travel – not a total substitute long term but we have learned a great deal. Telehealth and conducting clinical trials in a more remote fashion was already being developed but this has been given a big fast forward and ultimately will bring great benefit to the many thousands of Australians living in regional and rural areas through better access to clinical trials and healthcare in general.

The CAP remain committed to playing our part in providing advice from a consumer point of view to the ANZUP membership and the ever growing research portfolio. We are up to the challenges and opportunities that will no doubt be presented to us in the year ahead and would like to mark the year just completed as one for the history books.
On Tuesday 10 September 2019, ANZUP held its 6th annual Sydney Below the Belt Pedalthon, and 8th Pedalthon event overall.

ANZUP’s major fundraising event is held in Sydney and Melbourne each year, and every cent raised through the Below the Belt Pedalthon goes directly towards clinical trial research via the Below the Belt Research Fund. This funding initiative supports ANZUP members to develop novel research projects. To date, this funding has been awarded to 24 ANZUP members to help gather the evidence needed to develop full scale clinical research studies.

ANZUP’s goal is to raise enough funds to be able to fully support its own trials, and the Pedalthon strongly supports a step in that direction.

The event was held at the iconic Sydney Motorsport Park, Eastern Creek and raised over $160,000, which contributed to the $1,750,000 raised in total since the Pedalthon was launched in 2014.

We welcomed 176 riders across 35 teams, all ages and abilities from cycling superstars, to weekend riders and everyone in between. We were delighted to have corporate, pharma, medical and community teams participating in the event. ANZUP members also hit the track; the ANZUP All Stars, ANZUP Dream Team, Pato Pedalos and Associate Professor Craig Gedye riding with the Quarry Mining team.

The three-hour event was competitive with teams fighting for accolades both on and off the track. NSW Police clocked up an impressive 164 laps, taking home not only the award for most laps, but also fastest male lap and fastest sprint.
Other riders took home the trophy due to their incredible fundraising efforts; the ANZUP All Stars team raised over $10,000 for the Below the Belt Research Fund, while ANZUP member Professor Peter Grimison was the highest fundraiser, raising $5,864 through his own individual efforts.

Our thanks goes to our wonderful Platinum Sponsors, Morton Real Estate and Homely, Gold Sponsor GenesisCare, and Silver Sponsors, Pfizer Oncology and Northshore Mitsubishi, as well as our very generous supporters and donors, for helping this event take place.

The 3rd annual Melbourne Below the Belt Pedalthon was scheduled for Sunday 15 March 2020. However, due to unforeseen circumstances surrounding the COVID-19 pandemic, this community event has been postponed to the second half of 2020.

The Melbourne Pedalthon was shaping up to be a great day, with 46 enthusiastic teams entering into our Race Challenge and Family Challenge, along with 5 keen individual riders. A new event registration was introduced, the Sideline Supporter, for those who wanted to fundraise for the Research Fund but were unable to race in the Pedalthon. This proved successful with 5 of our ANZUP community registering as Sideline Supporters.

At the time the Annual Report went to print, our new date for Melbourne was yet to be confirmed, but we are very excited to keep building on the $96,000 raised and 184 riders registered so far. We are so grateful for the support of our Venue Sponsor, Melbourne Racing Club Foundation, Platinum Sponsor Bristol Myers-Squibb, Gold Sponsor GenesisCare and Silver Sponsor Ipsen, and all our riders and supporters, in these uncertain times.
Thanks to our 2019/20 Pedalthon sponsors and supporters

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While we were set a very high benchmark on the back of our 2018 ASM, I think thanks to an outstanding Convening Committee and Faculty, we managed to deliver, yet again, a high quality and innovative program that had something for everyone!

The theme ‘Making Connections’, was more relevant than ever bringing together a superb line up of international and national speakers under the one roof. It was also a great opportunity for people to connect with their peers, catch up with old colleagues and make new friends.

Over the three days, we were treated to the most up to date scientific presentations from our impressive international faculty: Kelly Parsons, Phuoc Tran, Alison Birtle, Catherine Paterson and Betsy Plimack who shared their insights and experience with more than 400 attendees.

The ASM kicked off with an array of pre-conference meetings on Sunday including the ANZUP PCFA Nurses Symposium, the Translational Research Symposium and the MDT Masterclass. We are very grateful to all the chairs for their efforts in delivering such thought provoking sessions.

On Sunday we also held our annual free Community Engagement Forum featuring presentations and panel discussions covering quality of life, treatment choices, survivorship, impacts on intimacy and the cost of cancer care. This forum gave the public the opportunity to engage with an experienced team of healthcare professionals and patient advocates, while learning about ANZUP and our clinical trials research program.

The day concluded with another excellent ANZUPx session, which we introduced at our ASM in 2018. This year Jane Turner gave us a thought provoking talk on “Touching the humanity: making authentic connections” followed by Declan Murphy entertaining us with some insights into avoiding obsolescence as a cancer surgeon.

The evening symposium was thoroughly entertaining. With the theme ‘The Art of Connecting’ we heard from our gifted faculty Kelly Parsons, an award-winning author, Alasdair Foster, Professor of Culture in Community and finally Alison Birtle treating us to her rendition of Send in the Clowns showing us how connecting through creativity can help with the stresses of work / life demands while caring for our cancer patients.

The Scientific Program on Monday and Tuesday involved close to 50 presentations, including a very interesting and stimulating discussion at the Tuesday breakfast session: ‘Is Social Media Worth the Risk for Healthcare Professionals’, ably chaired by Haryana Dhillon and featuring Henry Woo, Craig Gedye, Belinda Jago and the ever delightful social media expert Josh Britt.

Attendees were also fortunate to hear from ANZUP Chair and ENZAMET Co-Chair Ian Davis share the ENZAMET results, as presented at the ASCO plenary session in June 2019. The ANZUP-led trial showed a 33% improvement in overall survival and a 60% improvement in progression-free survival, for men with metastatic hormone sensitive prostate cancer who received enzalutamide in addition to the standard of care therapy (androgen deprivation therapy, ADT), with or without docetaxel chemotherapy.

This year we saw our Twitter engagement reach close to 2.8 million #ANZUP19 impressions and over 1,600 tweets – with Haryana Dhillon, Ian Davis and Henry Woo as key social media influencers. Attendance was impressive with close to 400 delegates – all testament to the high quality, collegial, educational, entertaining ASM for which ANZUP has become renowned.

Thank you to every speaker, sponsor, chair, delegate, participant, committee member and organiser for your contribution. We look forward to seeing you in Adelaide for #ANZUP21.

Associate Professor David Pryor
ANZUP 2019 ASM Convenor
ANZUP ASM 2019 highlights

“...another high quality and innovative program that had something for everyone.”

“...all testament to the high quality, collegial, educational, entertaining ASM for which ANZUP has become world renowned.”
“One cannot help feeling so good meeting so many clever and passionate people.”

“It was also a great opportunity for people to connect with their peers, catch up with old colleagues and make new friends.”
Thanks to our 2019 ASM sponsors

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Trade Exhibitors
Grants and Awards

Infrastructure Grants
Funds provided by Cancer Australia to support ANZUP infrastructure are managed by the University of Sydney NHMRC Clinical Trials Centre and therefore not reported in the financial accounts of ANZUP unless transferred in support of specific expenses incurred by ANZUP. Grants contributing to ANZUP infrastructure costs during the 2019-20 period are outlined below.

Funding
Cancer Australia Infrastructure Grant: 1 July 2018 to 30 June 2021- $1,500,000 awarded to ANZUP and our collaborator on the grant NHMRC CTC. During this reporting period $198,250 was transferred to ANZUP and was reported in the Annual Accounts.

Research Grants
Funds provided by Cancer Australia, the National Health and Medical Research Council and other bodies in support of trial coordination are also managed by the University of Sydney NHMRC Clinical Trials Centre and therefore are not reported in the financial accounts of ANZUP.

Grants awarded to ANZUP Cancer Trials Group during this reporting period are listed below:

BCGMM: A randomised phase III trial adding mitomycin to BCG as adjuvant intravesical therapy for high-risk, non-muscle-invasive bladder cancer. Funding Cancer Australia $457,143. 2013-2018. No funds were transferred to ANZUP during the reporting period.

BL.12: A Multicentre Randomised Phase II Trial Comparing Nab-Paclitaxel to Paclitaxel in Patients with Advanced Urothelial Cancer Progressing on or after a Platinum Containing Regimen. Funding NCIC Clinical Trials Group $1,384,662, Specialised Therapeutics $250,000: 2015-2018. During this period $4,823 was transferred to ANZUP and reported in the annual accounts.

DASL-HiCaP: A randomised phase III double-blind, placebo-controlled trial of adding darolutamide to androgen deprivation therapy and definitive or salvage radiation in very high risk, clinically localised prostate cancer. Funding by Bayer $33,777,579 USD. During this period $550,000 USD was transferred to ANZUP and reported in the annual accounts.

ENZADAR: A randomised phase III trial of Enzalutamide in first line androgen deprivation therapy for metastatic prostate cancer. Funding Astellas $17,131,966: 2014-2020. During this reporting period $325,049 was transferred to ANZUP and was reported in the Annual Accounts.

ENZAMET: A randomised phase III trial of Enzalutamide in high risk, clinically localised prostate cancer. Funding by Merck Sharp & Dohme $54,635 was received during the period. Funding Astellas $17,131,966: 2014-2020. During this period $275,000 was transferred to ANZUP and was reported in the Annual Accounts.

KEYPAD: A phase II trial using pembrolizumab and pembrolizumab in clear cell renal carcinoma. Funding by Merck Sharp & Dohme and Amgen $2,454,925. During this reporting period $339,699 was received and is reported in the annual accounts.

Pain Free TRUS B: A placebo-controlled, randomised trial of methoxyflurane to reduce the discomfort of prostate biopsy. Funding Cancer Australia $354,764 Prostate Cancer Foundation of Australia $242,331: 2015-2018. During this reporting period, no funds were transferred to ANZUP.

PCR MIB: Pembrolizumab with ChemoRadiotherapy as treatment for Muscle Invasive Bladder Cancer. Grant funding support from Merck Sharp & Dohme (Australia), $455,800 to conduct the study, anticipated to take up to 5 years. $54,635 was received during the reporting period, and is reported in the annual accounts.

Phase III Accelerated BEP (Cancer Australia and Cancer Council Australia): A randomised trial of accelerated versus standard BEP chemotherapy for intermediate and poor risk advanced germ cell tumours. Funding Cancer Australia $363,583, Cancer Council Australia $222,000: 2013-2018. No funds were transferred to ANZUP during the reporting period.

TheraP: An open label, randomised, stratified, 2-arm, multicentre phase II trial of Lu-PSMA617 theranostic versus cabazitaxel in progressive metastatic castration resistant prostate cancer. Funding received from IPSEN and Endocyte $2,525,000. During this reporting period $775,000 was received and reported in the annual accounts.

TIGER: A randomised phase III trial comparing conventional dose chemotherapy using paclitaxel, ifosfamide, cisplatin (TIP) with high-dose chemotherapy using mobilising paclitaxel plus ifosfamide followed by high-dose carboplatin and etoposide (Ti-CE) as first salvage treatment in relapsed or refractory germ cell tumours (TIGER). Funding Movember $540,000. During this period $75,000 was received and is reported in the Annual Accounts.

UNICAB: A phase II Trial Of Single Agent Cabozantinib In Patients With Locally Advanced Or Metastatic Non-Clear Cell Renal Cell Carcinoma Post Immunotherapy Or Who Are Unsuitable For Immunotherapy. Funding from IPSEN $1,173,201. During this reporting period $250,000 was received and reported in the annual accounts.

UNISoN: A phase II sequential cohort trial of single agent nivolumab, then combination ipilimumab + nivolumab in metastatic or unresectable non-clear cell renal cell carcinoma. Funding from Bristol Myers Squibb $1,681,822. During this reporting period $420,455 was received and is reported in the annual accounts.

All funds received are utilised for the conduct of trial activity as performed by third party organisations under the direction of ANZUP.
## Participating Centres

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** * * Active, not recruiting (in followup)
### Rest of the world

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Presentations

ENZAMET
ASCO, 2 June 2019
Plenary presentation by Professor Christopher J. Sweeney, MBBS.
Overall survival (OS) results of a phase III randomized trial of standard-of-care therapy with or without enzalutamide for metastatic hormone-sensitive prostate cancer (mHSPC): ENZAMET (ANZUP 1304), an ANZUP-led international cooperative group trial.

ENZAMET
MOGA ASM, 16 August 2019
Presentation by Professor Ian D. Davies
Overall survival (OS) Results of a Phase III Randomized Trial of Standard of Care Therapy with or without enzalutamide for a Metastatic Hormone-Sensitive Prostate Cancer (mHSPC): ENZAMET (ANZUP 1304), an ANZUP-led International Co-operative Group Trial.

SORCE
ESMO Congress, 28 September 2019
Presentation by Professor Tim Eisen on behalf of the SORCE Trial Management Group
Primary Efficacy Analysis Results From The SORCE trial (RE05): Adjuvant sorafenib for renal cell carcinoma at intermediate or high risk of relapse: an international, randomised double blind phase III trial led by the MRC CTU at UCL.

ENZAMET
ESMO Congress, 29 September 2019
Presentation by Professor Martin Stockler
Health-related quality of life (HRQL) in a randomized phase 3 trial of enzalutamide with standard first line therapy for metastatic, hormone-sensitive prostate cancer (mHSPC): ENZAMET (ANZUP 1304), an ANZUP-led, international, co-operative group trial.

Publications

ENZAMET
NEJM, 2 June 2019
Enzalutamide with Standard First-Line Therapy in Metastatic Prostate Cancer

TheraP
BJU, 28 October 2019
TheraP: a randomized phase II trial of 177Lu-PSMA-617 theranostic treatment vs cabazitaxel in progressive metastatic castration-resistant prostate cancer (Clinical Trial Protocol ANZUP 1603)
Michael S. Hofman, Louise Emmett, John Violet, Alison Y. Zhang, Nicola J. Lawrence, Martin Stockler, Roslyn J. Francis, Amir Iravani, Scott Williams, Arun Azad, Andrew Martin, Margaret McJannett, ANZUP TheraP team and Ian D. Davis.

proPSMA
The Lancet, 22 March 2020
Prostate-specific membrane antigen PET-CT in patients with high-risk prostate cancer before curative-intent surgery or radiotherapy (proPSMA): a prospective, randomised, multicentre study.
Michael S Hofman, Nathan Lawrentschuk, Roslyn J Francis, Colin Tang, Ian Vela, Paul Thomas, Natalie Rutherford, Jarad M Martin, Mark Frydenberg, Ramdave Shakker, Lih-Ming
Abstract TPS385: **DASL-HiCAP (ANZUP 1801):** The impact of darolutamide on standard therapy for localized very high-risk cancer of the prostate – A randomized phase III double-blind, placebo-controlled trial of adding darolutamide to androgen deprivation therapy and definitive or salvage radiation in very high-risk, clinically localized prostate cancer.

First Author: Tamim Niazi, MD

Abstract 485: Pembrolizumab with chemoradiotherapy as treatment for muscle invasive bladder cancer: A planned interim analysis of safety and efficacy of the PCR-MIB phase II clinical trial (ANZUP 1502).

First Author: Andrew Weickhardt, FRACP, MBBS

Abstract TPS425: **P3BEP (ANZUP 1302):** An international randomized phase III trial of accelerated versus standard BEP chemotherapy for adult and paediatric male and female patients with intermediate and poor-risk metastatic germ cell tumors (GCTs).

First Author: Shalini Subramaniam, MBBS

Abstract TPS602: Adding mitomycin to Bacillus Calmette-Guérin as adjuvant intravesical therapy for high-risk, nonmuscle-invasive urothelial bladder cancer (BCG+MM; ANZUP 1301).

First Author: Elizabeth Liow, MBBS, FRACP

Abstract TPS768: **UNISoN (ANZUP 1602):** Nivolumab then ipilimumab + nivolumab in advanced nonclear cell renal cell carcinoma.

First Author: Craig Gedye, PhD, FRACP
Annual Financial Report 2020

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General information

The financial statements cover ANZUP Cancer Trials Group Limited as an individual entity. The financial statements are presented in Australian dollars, which is ANZUP Cancer Trials Group Limited’s functional and presentation currency.

ANZUP Cancer Trials Group Limited is a not-for-profit unlisted public company limited by guarantee.

The financial statements were authorised for issue, in accordance with a resolution of directors, on 16 June 2020.
The directors of ANZUP Cancer Trials Group Limited (the company) submit their annual financial report for the year ended 31 March 2020.

Directors

The following persons were directors of the company during the whole of the year and up to the date of this report, unless otherwise stated:

- Ian Davis (Chair)
- Guy Toner (Deputy Chair)
- Nicholas Buchan
- Martin Dowling
- Joe Esposito
- Glenn Ferguson AM
- Linda Martin
- Henry Woo
- Shomik Sengupta

Information on directors

Professor Ian Davis Chair

Professor Ian Davis is chair of the ANZUP Board and of its Scientific Advisory Committee. He is a medical oncologist and is Professor of Medicine and Head of the Eastern Health Clinical School, Monash University and Eastern Health, in Melbourne, Australia. He is an NHMRC Practitioner Fellow. He holds honorary appointments with the Olivia Newton-John Cancer Research Institute (formerly Ludwig Institute for Cancer Research) and Austin Health, is an Associate Professor of the University of Melbourne, and Associate of the University of Sydney. His primary clinical interests are in urologic cancers, and his primary research interests are in cancer immunology and the biology of urologic cancers. Prof Davis is a member of the Medical & Scientific Committee and of the Standing Subcommittee on Research for the Cancer Council Victoria. He founded the Urologic Oncology Group of the Clinical Oncology Society of Australia (COSA), is a member of COSA Council, and previously a COSA Board director.

Associate Professor Guy Toner Deputy Chair

Associate Professor Guy Toner is a Consultant Medical Oncologist at Peter MacCallum Cancer Centre and Associate Professor of Medicine at the University of Melbourne. He is a graduate of the University of Melbourne and undertook sub-specialty training in medical oncology in Melbourne before spending 3 years at Memorial Sloan-Kettering Cancer Centre, New York. His clinical and research interests include all urological cancers with a particular interest in testicular cancer, which was the subject of his MD thesis. He has been an active member of other cooperative trials groups including as a past member of the Scientific Advisory Boards of the ANZ Breast Cancer Trials Group and the Australian Sarcoma Study Group. He was Head of the Medical Oncology Unit at Peter MacCallum Cancer Centre from 1993-2007. He was Chair of the ANZ Germ Cell Trials Group from 1995 until it merged to form ANZUP and since then he has been the Deputy Chair of ANZUP.

Dr Nick Buchan

Dr Nick Buchan is a Urologist based in Christchurch, New Zealand and works in both public and private practice. Nicks practice focuses on the diagnosis and management of urological cancers. Nick gained his experience in medical trials while on fellowship at the Vancouver Prostate Centre. The Vancouver Prostate Centre is one of the largest research and clinical centres in the world that focuses on translational research into prostatic diseases, prostate cancer in particular. Currently Nick is managing director of the Canterbury Urology Research Trust (CURT). CURT is a trust that conducts urological trials for contract research organisations (CROs) as well as its own investigator lead trials in urological conditions with the main focus being urological oncology. Nick is also a previous director of a privately owned hospital in Christchurch, Forte Health and managing director of a large Urology specialist practice, Urology Associates.
Mr Martin Dowling

Mr Martin Dowling has held executive and senior management level financial and commercial roles at some of the largest companies in the world. He has delivered in leadership roles against a broad portfolio of responsibilities across a range of industries including mining, mining services, manufacturing and engineering. He has a Bachelor of Commerce and MBA degree and is a Fellow of CPA Australia and a graduate member of the Australian Institute of Company Directors. He is committed to the pursuit of charitable and societal goals as a Director on not-for-profit boards and also actively in the local community.

Mr Joe Esposito

Mr Joe Esposito is a Melbourne director who owns a BOQ (Bank of Queensland) branch in the inner city suburb of Collingwood Victoria. Prior to this he was a management consultant and had over 20 years’ experience in corporate banking in Australia and New Zealand. He was also CEO of ASX listed Jetset Travelworld Limited between 2003 and 2006. Mr Esposito has a close affinity with the objectives of ANZUP and the needs of consumers. He has a Bachelor of Commerce and a Master of Applied Finance. He is a graduate member of the Australian Institute of Company Directors.

Mr Glenn Ferguson AM

Mr Glenn Ferguson AM is a Solicitor of the High Court of Australia and the Supreme Court of Queensland. He is a past President of the Law Council of Australia and past President of Lawasia the law association for Asia and the Pacific and a past President of the Queensland Law Society. He is also a Senior Counsellor with the Queensland Law Society and has previously chaired their professional standards committee. Glenn is a Founding Fellow of the Australian Academy of Law, a Fellow of the Australian Institute of Company Directors and a Fellow of the Australia Professional standards committee. He is currently Chair Lexon Insurance and a Governor of the College of Law. He has been appointed by both Federal and State Governments to various advisory boards and task forces in the legal, business and immigration sectors. In the 2015 Australia Day Honours, Glenn was made a Member of the Order of Australia “For significant service to the law and to the legal profession, both nationally and in the Asia Pacific region, and to the community”.

Ms Linda Martin

Linda Martin has recently retired after a broad career in Executive roles spanning public, private and not for profit organisations. She was previously CEO of not for profit Musculoskeletal Australia, a Senior Executive in the Victorian Public Service, working primarily in the health and community service sectors in large scale operational and project roles and a senior consultant in a strategic branding and marketing company. As Managing Director of a management consultancy firm she worked in diverse industries including banking, insurance, health, aged care, disability and transport sectors. Her work as an Executive coach and mentor continues. Linda has also been a lecturer in Social Work at the University of Melbourne, an industry representative on the Monash University, School of Public Health and Preventive Medicine Postgraduate Courses Committee and a Board Director of QEC. Linda’s focus has been on governance, strategic and business planning and reform and the development of strategic alliances. She is passionate about achieving consumer outcomes in health.

Professor Henry Woo

Professor Henry Woo is a urological surgeon who subspecialises in prostate disease. He is the Director of Uro-Oncology and Professor of Robotic Cancer Surgery at the Chris O’Brien Lifehouse. He is also Professor of Surgery at the Sydney Adventist Hospital Clinical School of the University of Sydney. He has published widely in major urological journals. He is an Associate Editor of the journal Prostate Cancer Prostatic Diseases and serves on the journal editorial boards of European Urology, BJUI, Prostate International, Asian Journal of Urology and World Journal of Men’s Health. He also serves on the board of the charitable Australian Urological Foundation(AUF) and is a member of the Executive Committee of the Asian Pacific Prostate Society (APPS). He is passionate about clinical trials and procuring the best evidenced based options for his patients. He also has particular interests in surgical education and the role of social media in learning and health advocacy.
Professor Shomik Sengupta
Shomik Sengupta is Professor of Surgery and deputy Head of School at the Eastern Health Clinical School, Monash University and a consultant urologist and Uro-Oncology lead at the Department of Urology, Eastern Health. Shomik has a practice with a uro-oncology subspecialty interest – including open, laparoscopic and robotic cancer surgery. Shomik also has a strong interest in urologic research, including involvement in clinical trials through the Australian and New Zealand Urogenital & Prostate (ANZUP) Cancer Trials Group, where he is a member of the Board and the Scientific Advisory Committee. Shomik has more than 100 original publications to date and has been an invited speaker, session chair and convenor at numerous scientific meetings.

Company Secretary
Ms Margaret McJannett was appointed secretary on 9 February 2011 and continues in office at the date of this report. Ms McJannett also serves as the company’s Chief Executive Officer.

Meetings of Directors
During the year, five meetings of directors were held. Attendances by each director were as follows:

<table>
<thead>
<tr>
<th>Directors’ meetings</th>
<th>Number eligible to attend</th>
<th>Number attended</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ian Davis</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>Guy Toner</td>
<td>5</td>
<td>4</td>
</tr>
<tr>
<td>Nicholas Buchan</td>
<td>5</td>
<td>4</td>
</tr>
<tr>
<td>Martin Dowling</td>
<td>5</td>
<td>4</td>
</tr>
<tr>
<td>Joe Esposito</td>
<td>5</td>
<td>4</td>
</tr>
<tr>
<td>Glenn Ferguson AM</td>
<td>5</td>
<td>4</td>
</tr>
<tr>
<td>Linda Martin</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>Henry Woo</td>
<td>5</td>
<td>4</td>
</tr>
<tr>
<td>Shomik Sengupta</td>
<td>5</td>
<td>5</td>
</tr>
</tbody>
</table>

Principal activity
The mission of the Company is to conduct clinical trial research to improve treatment of Bladder, Kidney, Testicular, Penile and Prostate Cancers.

Objectives of the company
The objectives of the Company are to develop, foster and promote prostate and urogenital cancer research by:

- providing access to clinical trials for all appropriate Australian and New Zealand patients;
- increasing involvement of and collaboration with various professional disciplines in clinical and preclinical research;
- providing opportunities for clinical research;
- building systems to simplify and streamline clinical research of the highest quality;
- fostering a culture of research amongst all clinicians involved in the care of patients with urogenital cancers;
- providing training opportunities for the next generation of clinical researchers;
- providing for translational studies in prostate and other urogenital cancers, including tissue banking from clinical trials for further studies.

The company intends to meet these objectives through performing industry sponsored and other clinical trials, ensuring these trials are widely accessible to patients, creating strong links with Cancer Australia and other peak bodies, engaging professional disciplines at all levels of protocol development and implementation, and securing funding to support clinical research training positions.

Review of operations
The company’s net income for the year was $1,183,147 (2019: $118,924).
At 31 March 2020, the company had net assets of $4,866,161 (2019: $4,029,990).
Changes in state of affairs
There were no significant changes in the state of affairs of the company during the year ended 31 March 2020.

Subsequent events
No matters or circumstance have arisen since the end of the year that have significantly affected, or may significantly affect, the operations of the company, the results of these operations, or the state of affairs of the company in future years.

Future developments
Likely developments in the operations of the company and the expected results of those operations in future years have not been included in this report as the inclusion of such information is likely to result in unreasonable prejudice to the company.

Court proceedings
No person has applied for leave of Court to bring proceedings on behalf of the company or intervene in any proceedings to which the company is a party for the purpose of taking responsibility on behalf of the company for all or any part of those proceedings.

The company was not a party to any such proceedings during the year.

Environmental issues
The company’s operations are not regulated by any significant environmental regulation under a law of the Commonwealth or of a State or Territory.

Indemnification of officers and auditors
The company has paid premiums to insure each director against liabilities for costs and expenses incurred by them in defending any legal proceedings arising out of their conduct involving a wilful breach of duty in relation to the company. The amount of the premium paid during the period was $2,408.

Auditors’ independence declaration
A copy of the auditors’ independence declaration as required under section 307C of the Corporations Act 2001 is set out on the next page.

Signed in accordance with a resolution of Directors

Ian Davis
Chairman
Sydney, 16 June 2020
DECLARATION OF INDEPENDENCE BY PAUL CHEESEMAN TO THE DIRECTORS OF ANZUP CANCER TRIALS GROUP LIMITED

As lead auditor of ANZUP Cancer Trials Group Limited for the year ended 31 March 2020, I declare that, to the best of my knowledge and belief, there have been no contraventions of any applicable code of professional conduct in relation to the audit.

Paul Cheeseman
Partner

BDO East Coast Partnership
Sydney, 16 June 2020
### Statement of Profit or Loss and Other Comprehensive Income

For the year ended 31 March 2020

<table>
<thead>
<tr>
<th>Notes</th>
<th>2020</th>
<th>2019</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>$</td>
<td>$</td>
</tr>
<tr>
<td>Revenue</td>
<td>3</td>
<td>5,252,849</td>
</tr>
<tr>
<td>Employee benefits expenses</td>
<td>(985,986)</td>
<td>(775,642)</td>
</tr>
<tr>
<td>Trial and investigation support</td>
<td>4 (a)</td>
<td>(1,733,831)</td>
</tr>
<tr>
<td>Administration expenses</td>
<td>4 (b)</td>
<td>(1,349,884)</td>
</tr>
<tr>
<td><strong>Net current year surplus</strong></td>
<td></td>
<td><strong>1,183,148</strong></td>
</tr>
<tr>
<td><strong>Other comprehensive income for the year</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unrealised gains/(losses) on financial assets</td>
<td>(284,853)</td>
<td>85,109</td>
</tr>
<tr>
<td><strong>Total comprehensive income</strong></td>
<td></td>
<td><strong>898,295</strong></td>
</tr>
</tbody>
</table>

The above statement of profit or loss and other comprehensive income should be read in conjunction with the accompanying notes.
ANZUP Cancer Trials Group Limited
Statement of Financial Position
For the year ended 31 March 2020

<table>
<thead>
<tr>
<th>Notes</th>
<th>2020</th>
<th>2019</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>$</td>
<td>$</td>
</tr>
<tr>
<td></td>
<td>Current assets</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Cash and cash equivalents</td>
<td>2,324,857</td>
</tr>
<tr>
<td></td>
<td>Trade and other receivables</td>
<td>646,549</td>
</tr>
<tr>
<td></td>
<td>Total current assets</td>
<td>2,971,406</td>
</tr>
<tr>
<td></td>
<td>Total non-current assets</td>
<td>5,514,448</td>
</tr>
<tr>
<td></td>
<td>Current liabilities</td>
<td>3,542,457</td>
</tr>
<tr>
<td></td>
<td>Employee benefits</td>
<td>63,287</td>
</tr>
<tr>
<td></td>
<td>Lease liabilities</td>
<td>22,208</td>
</tr>
<tr>
<td></td>
<td>Total non-current liabilities</td>
<td>77,235</td>
</tr>
<tr>
<td></td>
<td>Equity</td>
<td>Retained earnings</td>
</tr>
<tr>
<td></td>
<td>Total equity</td>
<td>4,866,161</td>
</tr>
</tbody>
</table>

The above statement of financial position should be read in conjunction with the accompanying notes.
<table>
<thead>
<tr>
<th></th>
<th>Financial Assets Reserve $</th>
<th>Retained earnings $</th>
<th>Total equity $</th>
</tr>
</thead>
<tbody>
<tr>
<td>Balance at 1 April 2018</td>
<td>(22,985)</td>
<td>3,848,942</td>
<td>3,825,957</td>
</tr>
<tr>
<td>Net income for the year</td>
<td>-</td>
<td>118,924</td>
<td>118,924</td>
</tr>
<tr>
<td>Other comprehensive income for the year</td>
<td>85,109</td>
<td>-</td>
<td>85,109</td>
</tr>
<tr>
<td>Total comprehensive income for the year</td>
<td>85,109</td>
<td>118,924</td>
<td>204,033</td>
</tr>
<tr>
<td><strong>Balance as at 31 March 2019</strong></td>
<td><strong>62,124</strong></td>
<td><strong>3,967,866</strong></td>
<td><strong>4,029,990</strong></td>
</tr>
<tr>
<td>Balance at 1 April 2019</td>
<td>62,124</td>
<td>3,967,866</td>
<td>4,029,990</td>
</tr>
<tr>
<td>Net income for the year</td>
<td>-</td>
<td>1,183,148</td>
<td>1,183,148</td>
</tr>
<tr>
<td>Other comprehensive income for the year</td>
<td>(284,853)</td>
<td>-</td>
<td>(284,853)</td>
</tr>
<tr>
<td>Total comprehensive income for the year</td>
<td>(284,853)</td>
<td>1,183,148</td>
<td>898,295</td>
</tr>
<tr>
<td><strong>Balance as at 31 March 2020</strong></td>
<td><strong>(284,853)</strong></td>
<td><strong>5,151,014</strong></td>
<td><strong>4,866,161</strong></td>
</tr>
</tbody>
</table>

The above statement of changes in equity should be read in conjunction with the accompanying notes.
## ANZUP Cancer Trials Group Limited
### Statement of Cash Flows
For the year ended 31 March 2020

<table>
<thead>
<tr>
<th>Notes</th>
<th>2020</th>
<th>2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>$</td>
<td>$</td>
<td></td>
</tr>
</tbody>
</table>

### Cash flows from operating activities
- Receipts from grants (inclusive of GST) 4,670,776 3,530,913
- Receipts from sundry income (inclusive of GST) 1,181,147 960,789
- Receipts from donations (inclusive of GST) 386,588 376,005
- Interest received 12,381 9,621
- Interest paid (3,748) -
- Dividend, interest and distribution received 172,534 132,458
- Payments to suppliers and employees (4,451,857) (4,058,526)

**Net cash inflow from operating activities** 14 1,967,821 951,260

### Cash flows from investing activities
- Payments for office equipment 7 (6,748) (2,664)
- Net withdrawals/(contributions) in FVTOCI financial assets (1,282,025) (736,860)

**Net cash outflow from investing activities** (1,288,773) (824,633)

### Cash flows from financing activities
- Repayment of leases (21,252) -

**Net cash outflow from financing activities** (21,252) -

### Net increase/(decrease) in cash and cash equivalents
- 657,796 211,736

<table>
<thead>
<tr>
<th>Cash and cash equivalents at the beginning of the year</th>
<th>1,667,061</th>
<th>1,455,325</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cash and cash equivalents at the end of the year</td>
<td>2,324,857</td>
<td>1,667,061</td>
</tr>
</tbody>
</table>

The above statement of cash flows should be read in conjunction with the accompanying notes.
Note 1. Summary of significant accounting policies

This financial report covers ANZUP Cancer Trials Group Limited (the company) as an individual entity for the year ended 31 March 2020. The company is limited by guarantee and is incorporated and domiciled in Australia. The financial statements are presented in Australian dollars, which is the company's functional and presentation currency.

The company's accounting policies adopted in the preparation of the financial statements are set out below.

New, revised or amending Accounting Standards and Interpretations adopted

The company has adopted all of the new, revised or amending Accounting Standards and Interpretations issued by the Australian Accounting Standards Board (AASB) that are mandatory for the current reporting period. Any new, revised or amending Accounting Standards or Interpretations that are not yet mandatory have not been early adopted. The following Accounting Standards and Interpretations are most relevant to the Company:

**AASB 15 Revenue from Contracts with Customers**
The Company has adopted AASB 15 from 1 April 2019. The standard provides a single comprehensive model for revenue recognition. The core principle of the standard is that an entity shall recognise revenue to depict the transfer of promised goods or services to customers at an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The standard introduced a new contract-based revenue recognition model with a measurement approach that is based on an allocation of the transaction price. This is described further in the accounting policies below.

**AASB 16 Leases**
The Company has adopted AASB 16 from 1 April 2019. The standard replaces AASB 117 'Leases' and for lessees eliminates the classifications of operating leases and finance leases. Except for short-term leases and leases of low-value assets, right-of-use assets and corresponding lease liabilities are recognised in the statement of financial position. Straight-line operating lease expense recognition is replaced with a depreciation charge for the right-of-use assets (included in operating costs) and an interest expense on the recognised lease liabilities (included in finance costs).

In the earlier periods of the lease, the expenses associated with the lease under AASB 16 will be higher when compared to lease expenses under AASB 117. However, EBITDA (Earnings Before Interest, Tax, Depreciation and Amortisation) results improve as the operating expense is now replaced by interest expense and depreciation in profit or loss.

For classification within the statement of cash flows, the interest portion is disclosed in operating activities and the principal portion of the lease payments are separately disclosed in financing activities. For lessor accounting, the standard does not substantially change how a lessor accounts for leases.

**Impact of adoption**
AASB 15, AASB 1058 and AASB 16 were adopted using the modified retrospective approach and as such comparatives have not been restated.

There was no impact from the adoption of AASB 15 Revenue from contracts with customers and AASB 1058 income for not-for-profit entities on opening retained profits as at 1 April 2019.

**AASB 1058 Income for not-for-profit entities**
The Company has adopted AASB 1058 from 1 April 2019. This replaces AASB 1004 Contributions which determines the revenue recognition method for non-reciprocal contributions. AASB 1058 also introduces the recognition of revenue for transactions where the consideration to acquire an asset is significantly less than the fair value to enable the Company to further its objectives, and for the receipt of volunteer services. This is described further in the accounting policies below.
The impact on adoption of AASB 16 leases at 1 April 2019 was as follows:

<table>
<thead>
<tr>
<th>Description</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operating lease commitments as at 1 April 2019 (AASB 117)</td>
<td>$92,123</td>
</tr>
<tr>
<td>Short-term leases not recognised as a right-of-use asset (AASB 16)</td>
<td>-</td>
</tr>
<tr>
<td>Effect of discounting using the weighted average incremental borrowing rate of 4.5% as at the date of initial application</td>
<td>$8,838</td>
</tr>
<tr>
<td>Accumulated depreciation as at 1 April 2019 (AASB 16)</td>
<td>-</td>
</tr>
<tr>
<td>Right-of-use assets (AASB 16)</td>
<td>$83,285</td>
</tr>
<tr>
<td>Lease liabilities - current (AASB 16)</td>
<td>$22,209</td>
</tr>
<tr>
<td>Lease liabilities - non-current (AASB 16)</td>
<td>$39,825</td>
</tr>
<tr>
<td>Reduction in opening retained profits as at 1 April 2019</td>
<td>-</td>
</tr>
</tbody>
</table>

**Basis of preparation**

This financial report is a general purpose financial report which has been prepared in accordance with Australian Accounting Standards - Reduced Disclosure Requirements, including the Australian Accounting Interpretations and other authoritative pronouncements of the Australian Accounting Standards Board and the Australian Charities and Not-for-profits Commission Act 2012, as appropriate for not-for-profit oriented entities. These financial statements do not comply with International Financial Reporting Standards as issued by the International Accounting Standards Board (‘IASB’).

**Historical cost convention**

The financial report has been prepared on an accrual basis and is based on historical costs. Cost is based on the fair values of the consideration given in exchange for assets.

**(a) Going concern**

The financial report has been prepared on a going concern basis. Refer to Note 19 for considerations regarding economic dependence.

**(b) Income tax**

The company is exempt from the payment of income tax under section 50-5 of the Income Tax Assessment Act 1997. The company is a deductible gift recipient.

**(c) Revenue recognition**

Grants received on the condition that specified services are delivered or conditions are fulfilled are considered reciprocal. Such grants are initially recognised as a liability (deferred income) and revenue is recognised as services are performed or conditions fulfilled. Revenue from non-reciprocal grants is recognised when the company obtains control of the funds.

Donations are recognised when received by the company.

Sponsorship revenue is recognised over the period to which the sponsorship relates.

Annual Scientific Meeting (ASM) conference revenue is recognised during the year in which the event takes place. The company contracts a professional events co-ordinator to manage the staging of the ASM conference including the receipt of revenue and payment of expenses in relation to the event. The company has determined that it is impractical to establish control over the calculation and collection of its share of the net profits relating to the ASM conference prior to entry into the financial records.

Interest revenue is recognised as interest accrues using the effective interest method.

Other revenue is recognised in the year to which it relates.

**(d) Current and non-current classification**

Assets and liabilities are presented in the statement of financial position based on current and non-current classification.

An asset is current when: it is expected to be realised or intended to be sold or consumed in normal operating cycle; it is held primarily for the purpose of trading; it is expected to be realised within twelve months after the reporting period; or the asset is cash or cash equivalent unless restricted from being exchanged or used to settle a liability for at least twelve months after the reporting period. All other assets are classified as non-current.
A liability is current when: it is expected to be settled in normal operating cycle; it is due to be settled within twelve months after the reporting period; or there is no unconditional right to defer the settlement of the liability for at least twelve months after the reporting period. All other liabilities are classified as non-current.

(e) **Cash and cash equivalents**
Cash and cash equivalents includes cash on hand, deposits held at call with financial institutions and other short-term, highly liquid investments with original maturities of three months or less that are readily convertible to known amounts of cash which are subject to an insignificant risk of changes in value.

(f) **Plant and equipment**
Plant and equipment is stated at historical cost less accumulated depreciation and impairment. Historical cost includes expenditure that is directly attributable to the acquisition of the items.

The depreciation rate used for each class of plant and equipment is as follows:

Office equipment – reducing balance at 20%.

The residual values, useful lives and depreciation methods are reviewed, and adjusted if appropriate, at each reporting date.

An item of plant and equipment is derecognised upon disposal or when no further future economic benefit to the company.

Gains and losses between the carrying amount and the disposal proceeds are taken to profit and loss.

(g) **Trade and other receivables**
Trade receivables are initially recognised at fair value and subsequently measured at amortised cost using the effective interest method, less any provision for impairment. Trade receivables are generally due for settlement within 30 days.

Collectability of trade receivables is reviewed on an ongoing basis. Debts which are known to be uncollectable are written off by reducing the carrying amount directly. A provision for impairment of trade receivables is raised when there is objective evidence that the company will not be able to collect all amounts due according to the original terms of the receivables.

(h) **Right-of-use assets**
A right-of-use asset is recognised at the commencement date of a lease. The right-of-use asset is measured at cost, which comprises the initial amount of the lease liability, adjusted for, as applicable, any lease payments made at or before the commencement date net of any lease incentives received, any initial direct costs incurred, and, except where included in the cost of inventories, an estimate of costs expected to be incurred for dismantling and removing the underlying asset, and restoring the site or asset.

Right-of-use assets are amortised on a straight-line basis over the unexpired period of the lease or the estimated useful life of the asset, whichever is the shorter. Where the entity expects to obtain ownership of the leased asset at the end of the lease term, the depreciation is over its estimated useful life. Right-of-use assets are subject to impairment or adjusted for any remeasurement of lease liabilities.

(i) **Trade and other payables**
These amounts represent liabilities for goods and services provided to the company prior to the end of the financial year and which are unpaid. Due to their short-term nature they are measured at amortised cost and are not discounted. The amounts are unsecured and are usually paid within 30 days of recognition.

(j) **Deferred income**
The liability for deferred income is the unutilised amount of grants received on the condition that specified services are delivered or conditions fulfilled. The services are usually provided or conditions usually fulfilled within 12 months of receipt of the grant.

(k) **Lease liabilities**
A lease liability is recognised at the commencement date of a lease. The lease liability is initially recognised at the present value of the lease payments to be made over the term of the lease, discounted using the interest rate implicit in the lease or, if that rate cannot be readily determined, the Company’s incremental borrowing rate. Lease payments comprise of fixed payments less any lease incentives receivable, variable lease payments that depend on an index or a rate, amounts expected to be paid under residual value guarantees, exercise price of a purchase option when the exercise of the option is reasonably certain to occur, and any anticipated termination penalties. The variable lease payments that do not depend on an index or a rate are expensed in the period in which they are incurred.
Lease liabilities are measured at amortised cost using the effective interest method. The carrying amounts are remeasured if there is a change in the following: future lease payments arising from a change in an index or a rate used; residual guarantee; lease term; certainty of a purchase option and termination penalties. When a lease liability is remeasured, an adjustment is made to the corresponding right-of-use asset, or to profit or loss if the carrying amount of the right-of-use asset is fully written down.

(l) Employee benefits

   Short-term employee benefits
   Liabilities for wages and salaries, including non-monetary benefits, annual leave and long service leave expected to be settled within 12 months of the reporting date are recognised in current liabilities in respect of employees’ services up to the reporting date and are measured at the amounts expected to be paid when the liabilities are settled.

   Other long-term employee benefits
   The liability for annual leave and long service leave not expected to be settled within 12 months of the reporting date are recognised in non-current liabilities, provided there is an unconditional right to defer settlement of the liability. The liability is measured as the present value of expected future payments to be made in respect of services provided by employees up to the reporting date using the projected unit credit method. Consideration is given to expected future wage and salary levels, experience of employee departures and periods of service. Expected future payments are discounted using market yields at the reporting date on national government bonds with terms to maturity and currency that match, as closely as possible, the estimated future cash outflows.

(m) Goods and Services Tax (GST)

   Revenues, expenses and assets are recognised net of the amount of associated GST, unless the GST incurred is not recoverable from the taxation authority. In this case it is recognised as part of the cost of acquisition of the asset or as part of the expense.

   Receivables and payables are stated inclusive of the amount of GST receivable or payable. The net amount of GST recoverable from, or payable to, the taxation authority is included with other receivables or payables in the statement of financial position.

Cash flows are presented on a gross basis. The GST components of cash flows arising from investing or financing activities which are recoverable from, or payable to the taxation authority, are presented as operating cash flow.

(n) Other financial assets

   Other financial assets are initially measured at fair value. Classification is determined based on the purpose of the instrument. Financial assets are derecognised when the rights to receive cash flows have been transferred.

Note 2. Critical accounting judgements, estimates and assumptions

The preparation of the financial statements requires management to make judgements, estimates and assumptions that affect the reported amounts in the financial statements. Management continually evaluates its judgements and estimates in relation to assets, liabilities, contingent liabilities, revenue and expenses. Management bases its judgements, estimates and assumptions on historical experience and on other various factors, including expectations of future events, management believes to be reasonable under the circumstances. The resulting accounting judgements and estimates will seldom equal the related actual results. The judgements, estimates and assumptions that have a significant risk of causing a material adjustment to the carrying amounts of assets and liabilities are discussed below.

Estimation of useful lives of assets

The company determines the estimated useful lives and related depreciation charges for its plant and equipment. The useful lives could change significantly as a result of technical innovations or some other event. The depreciation charge will increase where the useful lives are less than previously estimated lives, or technically obsolete or non-strategic assets that have been abandoned or sold will be written off or written down.

Employee benefits provision

As discussed in note 1, the liability for employee benefits expected to be settled more than 12 months from the reporting date is recognised and measured at the present value of the estimated future cash flows to be made in respect of all employees at the reporting date. In determining the present value of the liability, estimates of attrition rates and pay increases through promotion and inflation have been taken into account.
## Note 3. Revenue

<table>
<thead>
<tr>
<th>Description</th>
<th>2020</th>
<th>2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grant income</td>
<td>3,297,088</td>
<td>2,764,059</td>
</tr>
<tr>
<td>Donations</td>
<td>386,588</td>
<td>376,005</td>
</tr>
<tr>
<td>Honorariums</td>
<td>31,136</td>
<td>22,494</td>
</tr>
<tr>
<td>Corporate Supporter Program</td>
<td>140,000</td>
<td>56,250</td>
</tr>
<tr>
<td>Sponsorship</td>
<td>381,151</td>
<td>157,181</td>
</tr>
<tr>
<td>Annual Scientific Meeting</td>
<td>756,580</td>
<td>700,579</td>
</tr>
<tr>
<td>Interest income</td>
<td>12,381</td>
<td>9,621</td>
</tr>
<tr>
<td>Investment income</td>
<td>172,535</td>
<td>132,458</td>
</tr>
<tr>
<td>Sundry income</td>
<td>11,010</td>
<td>10,170</td>
</tr>
<tr>
<td>Forex gain on bank revaluation</td>
<td>64,380</td>
<td>9,479</td>
</tr>
<tr>
<td></td>
<td><strong>5,252,849</strong></td>
<td><strong>4,238,296</strong></td>
</tr>
</tbody>
</table>

## Note 4 (a). Trial and investigation support

<table>
<thead>
<tr>
<th>Description</th>
<th>2020</th>
<th>2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grant funding</td>
<td>1,473,159</td>
<td>1,968,993</td>
</tr>
<tr>
<td>Grant funding: Below The Belt expense</td>
<td>260,672</td>
<td>272,307</td>
</tr>
<tr>
<td></td>
<td><strong>1,733,831</strong></td>
<td><strong>2,241,300</strong></td>
</tr>
</tbody>
</table>

## Note 4 (b). Administration expenses

<table>
<thead>
<tr>
<th>Description</th>
<th>2020</th>
<th>2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>Accounting and auditing fees</td>
<td>36,340</td>
<td>32,547</td>
</tr>
<tr>
<td>Annual Scientific Meeting expense</td>
<td>507,355</td>
<td>413,147</td>
</tr>
<tr>
<td>Consulting fees</td>
<td>95,742</td>
<td>38,127</td>
</tr>
<tr>
<td>Information technology</td>
<td>31,291</td>
<td>51,733</td>
</tr>
<tr>
<td>Insurance</td>
<td>25,555</td>
<td>20,998</td>
</tr>
<tr>
<td>Registration</td>
<td>-</td>
<td>422</td>
</tr>
<tr>
<td>Travel and accommodation</td>
<td>182,368</td>
<td>66,304</td>
</tr>
<tr>
<td>Catering and conference</td>
<td>245,915</td>
<td>155,638</td>
</tr>
<tr>
<td>Telephone and teleconferencing charges</td>
<td>18,672</td>
<td>9,086</td>
</tr>
<tr>
<td>Rent</td>
<td>-</td>
<td>25,000</td>
</tr>
<tr>
<td>Depreciation and amortisation</td>
<td>24,718</td>
<td>1,442</td>
</tr>
<tr>
<td>Marketing expenses</td>
<td>41,704</td>
<td>122,269</td>
</tr>
<tr>
<td>Sundry expenses</td>
<td>57,865</td>
<td>46,467</td>
</tr>
<tr>
<td>Pedalthon expenses</td>
<td>82,359</td>
<td>119,250</td>
</tr>
<tr>
<td></td>
<td><strong>1,349,884</strong></td>
<td><strong>1,102,430</strong></td>
</tr>
</tbody>
</table>

## Note 5. Current assets - cash and cash equivalents

<table>
<thead>
<tr>
<th>Description</th>
<th>2020</th>
<th>2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cash at bank</td>
<td>2,324,857</td>
<td>1,667,061</td>
</tr>
</tbody>
</table>

## Note 6. Current assets - trade and other receivables

<table>
<thead>
<tr>
<th>Description</th>
<th>2020</th>
<th>2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trade receivables</td>
<td>236,376</td>
<td>97,865</td>
</tr>
<tr>
<td>Other receivables</td>
<td>410,173</td>
<td>44,001</td>
</tr>
<tr>
<td></td>
<td><strong>646,549</strong></td>
<td><strong>141,866</strong></td>
</tr>
</tbody>
</table>
Note 7. Non-current assets- property, plant and equipment

Office equipment - at cost
24,981
18,233
Less accumulated depreciation
(16,276)
(14,159)
8,705
4,074

Movements in carrying amounts
Carrying amount at beginning of year
4,074
1,409
Additions
6,748
4,107
Depreciation expense
(2,117)
(1,442)
8,705
4,074

Note 8. Non-current assets- right-of-use-assets

Land and buildings – right-of-use
At cost
83,285
-
Less accumulated amortisation
(22,601)
-
Total right-of-use-assets at end of year
60,684
-

Movements in carrying amounts of right-of-use-assets
Land and buildings – right-of-use
Carrying amount at the beginning of the year
83,285
-
Amortisation charge
(22,601)
-
Carrying amount at the end of the year
60,684
-

The Company leases the office premises under an agreement a 3.75 year term, with no option to extend explicitly stated.

Note 9. Non-current assets – other financial assets

Managed funds
5,445,059
4,510,012

Note 10. Current liabilities - trade and other payables

Trade payables
12,906
359,592
Accruals
337,000
171,197
Deferred revenue
3,107,056
1,697,125
3,456,962
2,227,914

Note 11. Lease liabilities

Current
22,208
-
Non-current
39,825
-
Total lease liabilities
62,033
62,033

The Company has discounted the future lease payments using the weighted average incremental borrowing rate of 4.5% as at the date of initial application, being 1 April 2019.
Note 12. Remuneration of auditors

The following fees were paid or payable for services provided by the auditor:

<table>
<thead>
<tr>
<th>Service</th>
<th>2020</th>
<th>2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>Audit of the financial report</td>
<td>4,650</td>
<td>4,500</td>
</tr>
<tr>
<td>Other services - assistance with preparation of the financial report</td>
<td>2,600</td>
<td>2,500</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>7,250</strong></td>
<td><strong>7,000</strong></td>
</tr>
</tbody>
</table>

Note 13. Key management personnel disclosures

The aggregate compensation made to members of key management personnel of the company is set out below:

<table>
<thead>
<tr>
<th>Key management personnel compensation</th>
<th>2020</th>
<th>2019</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total</strong></td>
<td><strong>225,326</strong></td>
<td><strong>216,619</strong></td>
</tr>
</tbody>
</table>

Note 14. Reconciliation of cash flows from operations with net income for the year

<table>
<thead>
<tr>
<th>Component</th>
<th>2020</th>
<th>2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>Net income for the year</td>
<td>1,183,148</td>
<td>118,924</td>
</tr>
<tr>
<td>Depreciation and amortisation</td>
<td>24,718</td>
<td>1,442</td>
</tr>
<tr>
<td>Change in operating assets and liabilities:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(Increase) / Decrease in trade and other receivables</td>
<td>(504,683)</td>
<td>78,716</td>
</tr>
<tr>
<td>Increase in trade and other payables</td>
<td>1,229,048</td>
<td>745,248</td>
</tr>
<tr>
<td>Increase in employee benefits</td>
<td>35,590</td>
<td>6,930</td>
</tr>
<tr>
<td><strong>Net cash inflow from operating activities</strong></td>
<td>1,967,821</td>
<td>951,260</td>
</tr>
</tbody>
</table>

Note 15. Related party transactions

Key management personnel

Disclosures relating to key management personnel are set out in note 11.

Transactions with related parties

During the year, the company received honorariums of $31,136 (2019: $22,494). These honorariums were in relation to speaking engagements undertaken by Ian Davis.

Receivable from and payable to related parties

There were no trade receivables, trade payables or loans to or from related parties as at year end (2018: nil).

Note 16. After balance date events

No other matters or circumstances have arisen since the end of the year which may significantly affect the operations of the company, the results of those operations, or the state of affairs of the company in subsequent years.

Note 17. Contingent liabilities and capital commitments

The company has no contingent liabilities or capital commitments as at year end (2019: nil).
Note 18. Members’ guarantee

The company is limited by guarantee. If the company is wound up, each member of the company undertakes to contribute to the assets of the company an amount not exceeding $50 for payment of the debts and liabilities of the company including the costs of the winding up. This undertaking continues for one year after a member ceases to be a member of the company.

At 31 March 2020, the number of members was 1,724 (2019: 1,515).

Note 19. Economic dependence

On 31 January 2020, the World Health Organisation (WHO) announced a global health emergency because of a new strain of coronavirus originating in Wuhan, China (COVID-19 outbreak) and the risks to the international community as the virus spreads globally beyond its point of origin. Because of the rapid increase in exposure globally, on 11 March 2020, the WHO classified the COVID-19 outbreak as a pandemic.

The full impact of the COVID-19 outbreak continues to evolve at the date of this report, and therefore management are uncertain as to the full impact that the pandemic will have on the financial condition, liquidity, and future results of operations of the company. Management have performed an assessment with the following key points identified:

• Trials will continue to be conducted in line with government regulations issued, and with priority, participation and capacity taken into consideration.
• Planned events will be rescheduled as soon as the general health advisories allow.
• ANZUP maintains a strong and liquid balance sheet enabling it to continue to operate despite the general economic setbacks.

Management will continue to monitor the economic impact of this situation and the business as a whole.

Note 20. Company details

The company’s registered office is:

Level 6, Lifehouse Building
119-143 Missenden Road
Camperdown NSW 2050

The principal place of business of the company is:

Level 6, Lifehouse Building
119-143 Missenden Road
Camperdown NSW 2050
1. The financial statements, comprising the statement of profit or loss and other comprehensive income, statement of financial position, statement of cash flows, statement of changes in equity, and accompanying notes, are in accordance with the Australian Charities and Not-for-profits Commission Act 2012 (ACNC Act) and:
   a. comply with Australian Accounting Standards – Reduced Disclosure Requirements and the Division 60 of the Australian Charities and Not-for-profits Commission Regulation 2013; and
   b. give a true and fair view of the entity’s financial position as at 31 March 2020 and of its performance for the year ended on that date.

2. In the directors’ opinion, there are reasonable grounds to believe that the entity will be able to pay its debts as and when they become due and payable.

This declaration is made in accordance with a resolution of the Board of Directors and is signed for and on behalf of the directors by:

Ian Davis
Chairman

Sydney, 16 June 2020
INDEPENDENT AUDITOR’S REPORT

To the members of ANZUP Cancer Trials Group Limited


Qualified opinion

We have audited the financial report of ANZUP Cancer Trials Group Limited (the registered entity), which comprises the statement of financial position as at 31 March 2020, the statement of profit or loss and other comprehensive income, the statement of changes in equity and the statement of cash flows for the year then ended, and notes to the financial report, including a summary of significant accounting policies, and the responsible entities’ declaration.

In our opinion, except for the effects of the matter described in the Basis for qualified opinion section of our report, the accompanying financial report of ANZUP Cancer Trials Group Limited, is in accordance with Division 60 of the Australian Charities and Not-for-profits Commission Act 2012, including:

(i) Giving a true and fair view of the registered entity's financial position as at 31 March 2020 and of its financial performance for the year then ended; and

(ii) Complying with Australian Accounting Standards – Reduced Disclosure Requirements and Division 60 of the Australian Charities and Not-for-profits Commission Regulation 2013.

Basis for qualified opinion

Cash donations are a significant source of fundraising revenue for the registered entity. The registered entity has determined that it is impracticable to establish control over the collection of cash donations prior to entry into its financial records. Accordingly, as the evidence available to us regarding fundraising revenue from this source was limited, our audit procedures with respect to cash donations had to be restricted to the amounts recorded in the financial records. We therefore are unable to express an opinion whether cash donations the registered entity recorded are complete.

Auditor’s Responsibility

We conducted our audit in accordance with Australian Auditing Standards. Our responsibilities under those standards are further described in the Auditor’s responsibilities for the audit of the Financial Report section of our report. We are independent of the registered entity in accordance with the auditor independence requirements of the Australian Charities and Not-for-profits Commission Act 2012 (ACNC Act) and the ethical requirements of the Accounting Professional and Ethical Standards Board’s APES 110 Code of Ethics for Professional Accountants (including Independence Standards) (the Code) that are relevant to our audit of the financial report in Australia. We have also fulfilled our other ethical responsibilities in accordance with the Code.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our qualified opinion.
Other information

Those charged with governance are responsible for the other information. The other information obtained at the date of this auditor’s report is information included in the Directors’ report for the year ended 31 March 2020, but does not include the financial report and our auditor’s report thereon.

Our opinion on the financial report does not cover the other information and accordingly we do not express any form of assurance conclusion thereon.

In connection with our audit of the financial report, our responsibility is to read the other information and, in doing so, consider whether the other information is materially inconsistent with the financial report or our knowledge obtained in the audit or otherwise appears to be materially misstated.

If, based on the work we have performed on the other information obtained prior to the date of this auditor’s report, we conclude that there is a material misstatement of this other information, we are required to report that fact. We have nothing to report in this regard.

Responsibilities of responsible entities for the Financial Report

The responsible entities of the registered entity are responsible for the preparation and fair presentation of the financial report in accordance with Australian Accounting Standards – Reduced Disclosure Requirements and the ACNC Act, and for such internal control as the responsible entities determine is necessary to enable the preparation of the financial report that is free from material misstatement, whether due to fraud or error.

In preparing the financial report, responsible entities are responsible for assessing the registered entity’s ability to continue as a going concern, disclosing, as applicable, matters related to going concern and using the going concern basis of accounting unless the responsible entities either intends to liquidate the registered entity or to cease operations, or has no realistic alternative but to do so.

Those charged with governance are responsible for overseeing the registered entity’s financial reporting process.

Auditor’s responsibilities for the audit of the Financial Report

Our objectives are to obtain reasonable assurance about whether the financial report as a whole is free from material misstatement, whether due to fraud or error, and to issue an auditor’s report that includes our opinion. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with the Australian Auditing Standards will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of this financial report.

A further description of our responsibilities for the audit of the financial report is located at the Auditing and Assurance Standards Board website (http://www.auasb.gov.au/Home.aspx) at:


This description forms part of our auditor’s report.

BDO East Coast Partnership

Paul Cheeseman
Partner

Sydney, 16 June 2020
Make a difference with ANZUP

We need your help to improve outcomes for people affected by these below the belt (prostate, testicular, penile, bladder and kidney) cancers and for future generations.

Any donation, large or small, goes straight into the hands of experts to find the answers we need.

To find out more or to donate please go to www.anzup.org.au/donate

How you can help

Kick off a pilot study

Invest in a pilot study to test the feasibility of promising drug therapies, surgical methods, post-operative care and palliative care options.

$50k–$250k

Support a clinical trial

Invest in a clinical trial to test the effectiveness, side effects and best dose of potential treatments for urogenital cancers.

$1m–$5m

Give a grant or fund a scholarship

Inspire our culture of research by providing a grant or scholarship to clinicians involved in the care of patients with urogenital cancer.

Be kind in-kind

Investment and support comes in all shapes and sizes. In-kind donations can include secretariat support, meeting room use and auctionable goods for fundraising.

Find out more

Visit us at www.anzup.org.au

• Find out about our trials
• Join Friends of ANZUP
• Donate and help fund a trial
• Get involved in below the belt fundraising events
• Read our member newsletter, UPdate
• Read our consumer magazine, A little below the belt

Follow us

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